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MASTER THESIS

Analysis, Evaluation, and Improvement of the Complaint Management System of a Growing Pharmaceutical Company in Hamburg

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The thesis is supervised in cooperation with the company AqVida GmbH.

Preface

During my internship at the pharmaceutical company AqVida GmbH, in the department of Pharmacovigilance especially in the complaint management system, I could recognise that the company is facing challenges in managing the complaints of their medicinal products. As the company is growing fast, there is a need for an adapted system for handling complaints.

I have been concerned with the questions: What are the critical process attributes in the complaint handling and how do they impact the process in the company? What are the current problems in the processing and evaluation of complaints and how can the complaint management system in the company be improved? I will pursue these questions in my master thesis in the following.

Acknowledgements

At this point, I would like to thank all those who supported and motivated me during the research and writing process of this Master thesis.

First and foremost, I would like to thank the Almighty God, who uniquely enables me to achieve my goals.

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Abstract

Objective: To examine and analyse the complaint management system of the growing pharmaceutical company AqVida GmbH in Hamburg.

Methods: A qualitative approach was used for data collection utilising two instruments: document analysis of the complaints from the year 2015 to 2020 and interviews at the company (1 focus group consisting of 2 participants, 2 face-to-face and 5 online interviews). The collected data were then analysed and presented in the results section.

Results: The finding of this study shows that the number of complaints is increasing in the company. As the processing time at the company according to their internal Standard Operating Procedure (SOP) is 10 working days only 14% of complaints were processed in a proper time in 2020. 24% of complaints took the processing time of less than one month, 35% complaints took the time of 1-3 months, whereas 27% of complaints were processed between 4-6 months. The reasons for the delayed responses were e.g. difficulties in time management, insufficient follow-up, no reminder system, or the absence of a specific investigator and manager for handling complaints. In order to resolve these issues and to improve the complaint handling system, strategies are presented within the course of this thesis.

Conclusion: Based on the qualitative research, it can be concluded that due to the increased number of complaints, the company needs an efficient system for complaint management. The reason for the increased number of complaints is the production and marketing progress of the company. The problems in complaint handling can be minimised by reorganising the process and implementing software to digitise and automate the process. There is a need for one manager who handles all complaints in the company. Proper follow-up should be done to avoid any delay in the evaluation and processing of complaints. Training and meetings on a regular basis are also very important to discuss the repetitive complaints and to take specific measures and actions to prevent these incidents in the future.

Key words:

Complaint management system, pharmaceutical company, complaint handling, qualitative approach

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List of Abbreviations

CAPAs	*Corrective Actions and Preventive Actions*
CPAs	*Critical Process Attributes*
EMA	*European Medicine Agency*
EU	*European Union*
FDF	*Finished Dosage Form*
GMP	*Good Manufacturing Practice*
MAs	*Marketing Authorisations*
PV	*Pharmacovigilance*
QA	*Quality Assurance*
QC	*Quality Control*
QP	*Qualified Person*
QPPV	*Qualified Person for Pharmacovigilance*
RA	*Regulatory Affairs*
SOPs	*Standard Operating Procedures*

1. Introduction

"Complaint is defined as a statement that something is wrong or not good enough" (Braga, 2007). In the pharmaceutical industry, complaint management is a crucial domain that requires particular focus because of its relevance to patient safety. Pharmaceutical companies must have a mechanism and adequate procedure to register, evaluate, investigate, and review complaints, including quality defects to protect public health (§19 - Arzneimittel- und Wirkstoffherstellungsverordnung (AMWHV)). In the event of a reported quality fault of a medicinal product that could result in a recall or irregular supply limit, all relevant competent authorities must be notified as soon as possible (European Union Guidelines to GMP, 2014). Generally, complaints in the pharmaceutical companies are related to the quality of the drug (Braga, 2007). "They can be about packaging material such as 'The bottle is leaking', 'The cap is difficult to open', 'A tablet in the blister is missing' or concern the aspect and effect of the product, e.g. 'There is no effect of the medicine', 'The tablet or solution colour is different' and so on". Complaint management needs customer feedback, the response from the manufacturer, and a follow-up to see if the customer was satisfied (Braga, 2007).

Complaint handling is a "Good Manufacturing Practice" (GMP) requirement (European Union Guidelines to GMP, 2014). Manufacturers must maintain stringent adherence to current GMP with regards to their processes, controls, and product manufacturing for pharmaceutical and drug regulatory compliance (Braga, 2007). Pharmaceutical companies must focus on the complaints concerning defective products so that they may be thoroughly investigated, and necessary action should be taken to prevent recurrence (Kumar, Jha, 2015). The ability of a pharmaceutical company to manage the reports and monitor adverse effects is important, but different international requirements for adverse event reporting and product complaint handling cause difficulty in automating processes and implementing SOPs. "Therefore, it is necessary for companies to successfully resolve incidents and continue a path to innovation" (McElroy, 2019). The role of the complaint management system in the pharmaceutical industry cannot be overstated, so this thesis aims to analyse and evaluate the quality complaint handling system of a growing pharmaceutical company in Hamburg.

The thesis comprises seven chapters. At first, the introductory section describes the company information, background of complaints and the complaint management system of the company. The second chapter then explains the research questions and objectives of the research study.

This is followed by the third chapter, which describes the method, survey instruments, the data collection and the data analysis steps. It begins with the selection of a qualitative approach and the development of the interview guide. The data collection process includes document analysis of complaints, conducting a focus group, and face-to-face interviews based on a semi-structured interview guide. The data analysis process includes transcription and content analysis. Finally, the obtained data are interpreted and presented in results in the fourth chapter. Following that, a discussion of findings and some limitations of the applied method is also discussed in the fifth chapter. The sixth chapter presents the strategies to improve the complaint management system and the evaluation of the strategies. In the last chapter, a brief outlook concludes the work.

1.1. Company Information

AqVida GmbH is a German pharmaceutical company, with a clear focus to develop, register and market oncology generics. It was founded in 2005 with a focus on trading active pharmaceutical ingredients to unregulated and semi-regulated markets. The company received its first Finished Dosage Form (FDF) registration in the semi-regulated market in 2008, with further FDF registrations in European Union (EU) in 2010. The first finished product was approved in Germany in 2012, since then there was a steady increase of marketing authorisations (MAs). Until 2015, the medicinal products were not sold under the company's brand name and the products were manufactured at contract manufacturers, mainly located in foreign countries. In 2016, the company opened its manufacturing site in Dassow, Germany, which is equipped to produce liquid medicines for parenteral administration. In addition to that, AqVida GmbH has actively developed solid and liquid medicinal products and successfully brought them to market approvals (Internal company presentation, 2018). In total, AqVida in July 2021 held MAs for eleven different medicinal products within the EU, of which six were manufactured at its site (Internal statistic AqVida, 2021).

AqVida has different departments including supply chain, production, Quality Control (QC), Regulatory Affairs (RA), and Pharmacovigilance (PV). The complaint management system is currently handled by the latter with the support of other departments. In the following section, the PV department will be explained in more detail.

1.2. Pharmacovigilance Department

"Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse reactions and other medicine-related problems"

(European Medicines Agency (EMA), 2015). The European Medicines Agency (EMA) operates the system on behalf of the EU medicines regulatory network" (EMA, 2020).

The primary objectives of PV are to:

- provide information that enables the company to license its medicinal product,
- improve patient care, public health, and medication utilisation security,
- take care of ongoing and systematic monitoring of the safety of products e.g. by accepting side effect reports or complaints from the customer (EMA, 2016; WHO, 2006).

Complaints belong more to the quality area than to drug safety. At AqVida GmbH, however, the complaint management system is supervised by the PV department, as the complaints may lead to a suspected side effect, which the Qualified Person for Pharmacovigilance (QPPV) must report to the authorities within strict deadlines. The QPPV is the contact point for authorities and contact person for PV inspections 24 hours a day. The responsibility of the QPPV/Graduated plan officer is to ensure that all incoming complaints must be recorded systematically according to the EU-GMP Guide. The tasks of the QPPV/Graduated plan officer as well as the other employees in the PV department are described in more detail in the following sections.

Employees in Pharmacovigilance

Qualified Person for Pharmacovigilance (QPPV)

The European Qualified Person for Pharmacovigilance (QPPV), and the German Graduated plan officer (Stufenplanbeauftragte) are synonymous in this thesis. As an international and national responsible person, the QPPV/Graduated plan officer keeps track of the benefit-risk profile of all medicinal products of AqVida GmbH, for which they set up and maintain a PV system. They collect and evaluate all known reports about drug risks, coordinate necessary measures and systematically record all complaints. In contrast to QPPV, the Graduated plan officer also evaluates the pharmaceutical deficiencies of a drug. However, in the following sections of this thesis, only the term QPPV is used to maintain clarity.

According to section 19 paragraph 1 of the Arzneimittel und Wirkstoffherstellungsverordnung– AMWHV (*German Medicinal Products and Active Substance Manufacturing Ordinance*), "the QPPV is responsible for collecting all known reports of drug risks following a written or electronic procedure and for systematically recording all complaints. In doing so, the immediate

review of the reports is to be initiated without delay and evaluated to determine whether a drug risk exists, how serious it is and what measures are required to avert the risk. The necessary measures are to be coordinated and brought to the attention of the Qualified Person (QP) under section 14 of the Arzneimittelgesetz-AMG (*German Medicines Law*) so that he or she can take the measures necessary on his or her part, if necessary, especially if the problem is about quality of the product" (AMWHV § 19 (1), 2021).

Qualified Person (QP)

The QP ensures the production and testing of all batches of pharmaceutical products by following the regulations governing the marketing of manufactured pharmaceutical products. According to section 14 of the German Medicines Act, "the QP shall certify compliance with these regulations for each batch of medicinal products in a continuous register or a comparable document before the medicinal products are placed on the market" (AMG § 14, 2021).

Pharmacovigilance (PV) Managers

The PV managers are the employees in the PV department who ensures a positive benefit-risk profile of AqVida's medicinal products and perform tasks assigned to them by the QPPV (Internal SOP, PV-SOP-00-01V1, 2021).

1.3. Background of Complaints

According to EU-GMP Guide Chapter 8, pharmaceutical companies must review all complaints and other information concerning potentially defective products carefully according to written procedures. A written protocol should be in place that outlines the steps to be followed when receiving a complaint. All complaints must be documented and assessed to establish if they represent a potential quality defect or other issues (European Union Guidelines to GMP, 2014).

Similarly, section 19 of the Arzneimittel und Wirkstoffherstellungsverordnung – AMWHV (*German Medicinal Products and Active Substance Manufacturing Ordinance*) prescribes a binding procedure for the pharmaceutical company in the event of product complaints (AMWHV § 19). The QPPV together with the QP must be made aware of any complaint and be actively involved in the investigation and subsequent recall (European Union Guidelines to GMP, 2014).

AqVida GmbH fulfils the requirement of the EU-GMP Guide by having a written procedure in the SOP for complaint handling which is explained in the next chapter.

1.4. Complaint Management System of AqVida GmbH

Complaint management is the process of accepting, reviewing, tracking down the reason, and giving feedback over a complaint issued by the customer (Ombudsman, 2021). The foremost priority of developing this system for complaint management is to ensure the quality of products as well as to fulfil the obligation of Arzneimittel und Wirkstoffherstellungsverordnung (*German Medicinal Products and Active Substance Manufacturing Ordinance*) – AMWH § 19.

The complaint management system of AqVida GmbH consists of the following steps.

- Complaint acceptance
- Complaint processing
- Complaint evaluation
- Complaint response letter

The following section describes the complaint handling process in detail. A schematic overview of the complaint acceptance process is shown in Figure 1 on page 6 and of complaint processing in Figure 2 on page 10.

1.4.1. Acceptance of Complaint

The process gets initiated with the receipt of a customer complaint. At both locations of AqVida GmbH (Hamburg and Dassow), complaints are taken by all employees and convey to the responsible PV manager and QPPV within 24 hours. This is important because a potential adverse reaction might be noticed, which may have to be reported to the authorities within stringent timelines. Therefore, the customer must provide all relevant information about the complaint product, i.e. name of the product, size/strength of package, batch number, expiry date, and reason of complaint. In addition, in some cases, the complaint sample has to be returned to the company, in case needed for the investigation. A number is assigned to the complaint by the PV manager who subsequently enters all the information gathered during the complaint intake into the complaint acceptance form, the complaint overview table and the processing form.

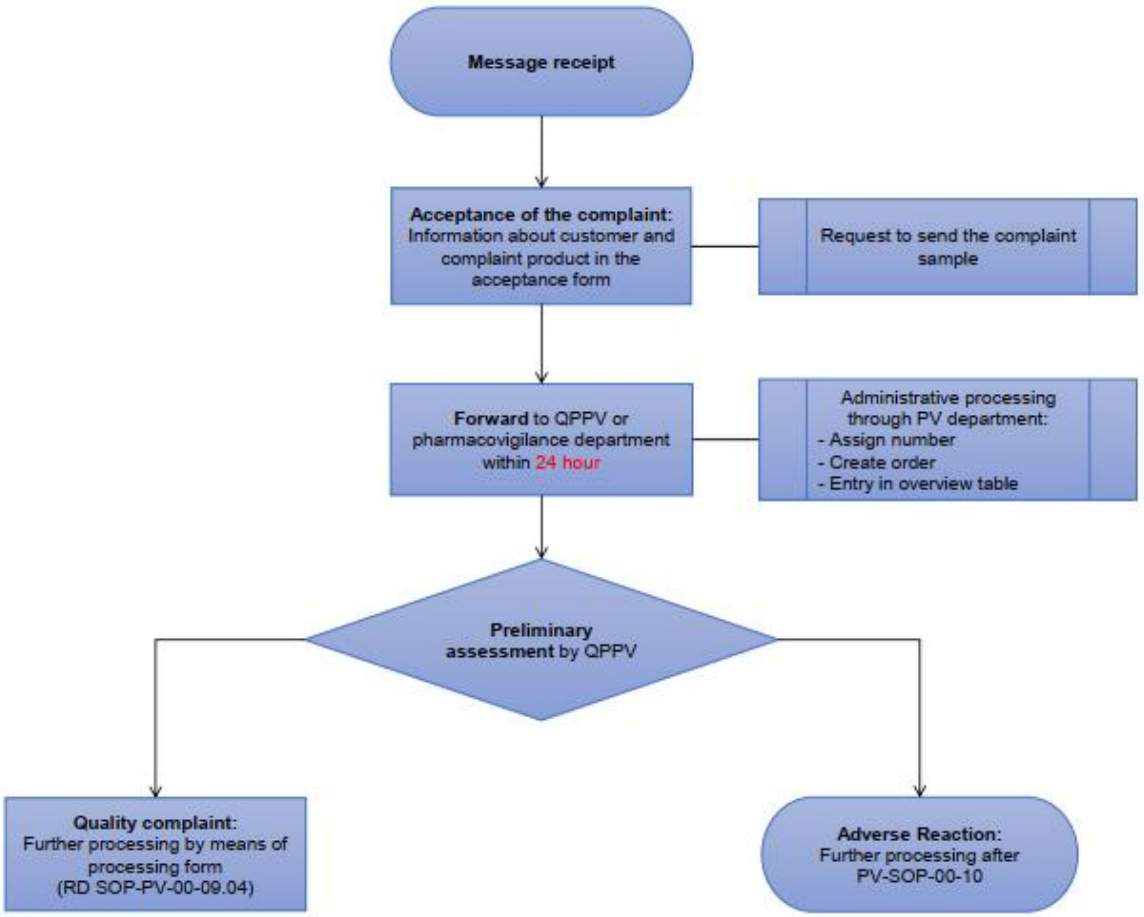

Figure 1: Flowchart of the complaint acceptance process

(Source: Internal SOP of AqVida in own representation)

In the complaint acceptance form (*see Appendix A: Complaint Acceptance Form*), the QPPV conducts a preliminary evaluation and classifies the incoming complaint as a quality complaint, suspected adverse reaction or both (Internal SOP (PV-SOP-00-09 V3), 2021).

1.4.2. Internal Communication of Complaint

Whenever the incoming complaint is confirmed as quality related as per the acceptance form, the concerned PV manager supervises the procedure and conveys it to the following AqVida GmbH employees for thorough complaint processing.

- Head of Quality Control (QC)/Quality Assurance (QA)
- Head of the production
- QPPV/QP (Internal SOP, PV-SOP-00-09 V3, 2021) (*see Figure 2*).

1.4.3. External Communication of Complaint

After the complaint acceptance form has been filled out and the case has been communicated internally, the person making the complaint is informed by the responsible PV manager that the processing procedure has been started. The following information is transmitted or requested:

- Name and contact details of the responsible AqVida employee (usually the PV manager).
- Complaint number
- If information is missing for the complete completion of the complaint acceptance form, it will be requested.

1.4.4. Evaluation by Quality Control/Assurance department

In parallel with the Manufacturing, the complaint case is processed by the QC or QA department. This may include the following points:

- Examination of the complaint sample
- if necessary, examination of the return sample and other samples or batches
- Comparison with previous, similar complaints
- Resulting Corrective Actions and Preventive Actions (CAPAs), if applicable
- Further measures may help to clarify the respective facts.
- Evaluation of the defect
- Reasoning or investigation of the cause

After receipt and assessment of all information, the head of QC/QA enters an evaluation (causes of the complaint, any measures taken, result) of the complaint in the complaint processing form (*see Appendix B: Complaint Processing Form*) and then signs it.

1.4.5. Evaluation by the Production department

Parallel to the QC or QA, the complaint case is processed by the production department. This can include the following points, among others:

- Checking the batch documentation (production and packaging records) and, if necessary, carrying out further research to clarify the facts of the case.
- In coordination with the responsible PV manager: if necessary, questioning of the corresponding contract manufacturer

- Evaluation of the source material
- The reasoning or root cause analysis
- if necessary resulting CAPAs
- Further measures contribute to the clarification of the respective facts
- Evaluation of the defect

The head of the production decides which of these examinations are to be carried out and to what extent. Under certain circumstances, examinations going beyond the release specifications must be initiated and contract laboratories must be consulted, or, in the case of contract manufacturing of the medicinal product concerned, further information must be obtained from the contract manufacturer. After receiving and evaluating all the information, the head of the production enters an evaluation (causes of the complaint, any measures taken, result) of the complaint in the complaint processing form (*see Appendix B: Complaint Processing Form*) and then signs it.

1.4.6. Processing by Qualified Person for Pharmacovigilance/Qualified Person

After the complaint has been evaluated by the heads of QC/QA and production department, the QPPV or the QP examines the complaint by classifying it as per European Commission's criteria and dividing it into classes 1-3 if a defect can be identified (*see Table 1*). Furthermore, measures can be decided which should also enter in the complaint processing form (*see Appendix B: Complaint Processing Form*).

Table 1: Classification of complaint

Class	Description	Example
1	The defect is potentially life-threatening and could pose a serious health risk. → recall essential	Wrong product or starch, microbial or chemical contamination.
2	The defect may result in illness or inappropriate treatment and does not come under class I. → recall possible	Incorrect information, under-mixing, incorrect information in the package insert, inadequate closure with serious medical consequences.
3	The defect does not pose a significant health risk. → recall not essential	Poor quality of packing materials, wrong or missing batch numbers.
None	– No defect detectable; complaint unfounded.	particles found on the outside

(Source: PIC/S, 2017)

In addition, complaint measures and frequencies can be specified, which are also entered in the complaint form. These can be:

- Measures according to SOP Alarm and Action Plan
- Informing the responsible Authority
- Informing the manufacturer
- The first occurrence of the complaint
- Known problem, a solution is being worked out
- Known problem, a solution has been worked out

After everyone involved in the process has documented their contribution by signature, the complaint is closed with the final signature of QPPV/QP.

1.4.7. Response to the complaint

The QPPV, in collaboration with the corresponding PV manager, responds to the complaint in the form of a letter once the complaint has been evaluated and closed by the QPPV/QP. The response letter should be sent to the respective customer within 10 working days, even if not

all evaluations from QA/QC and the production department have been received. The date on which the concerned PV manager sends the letter to the customer should be mentioned on the complaint processing form (Internal SOP, PV-SOP-00-09 V3, 2021).

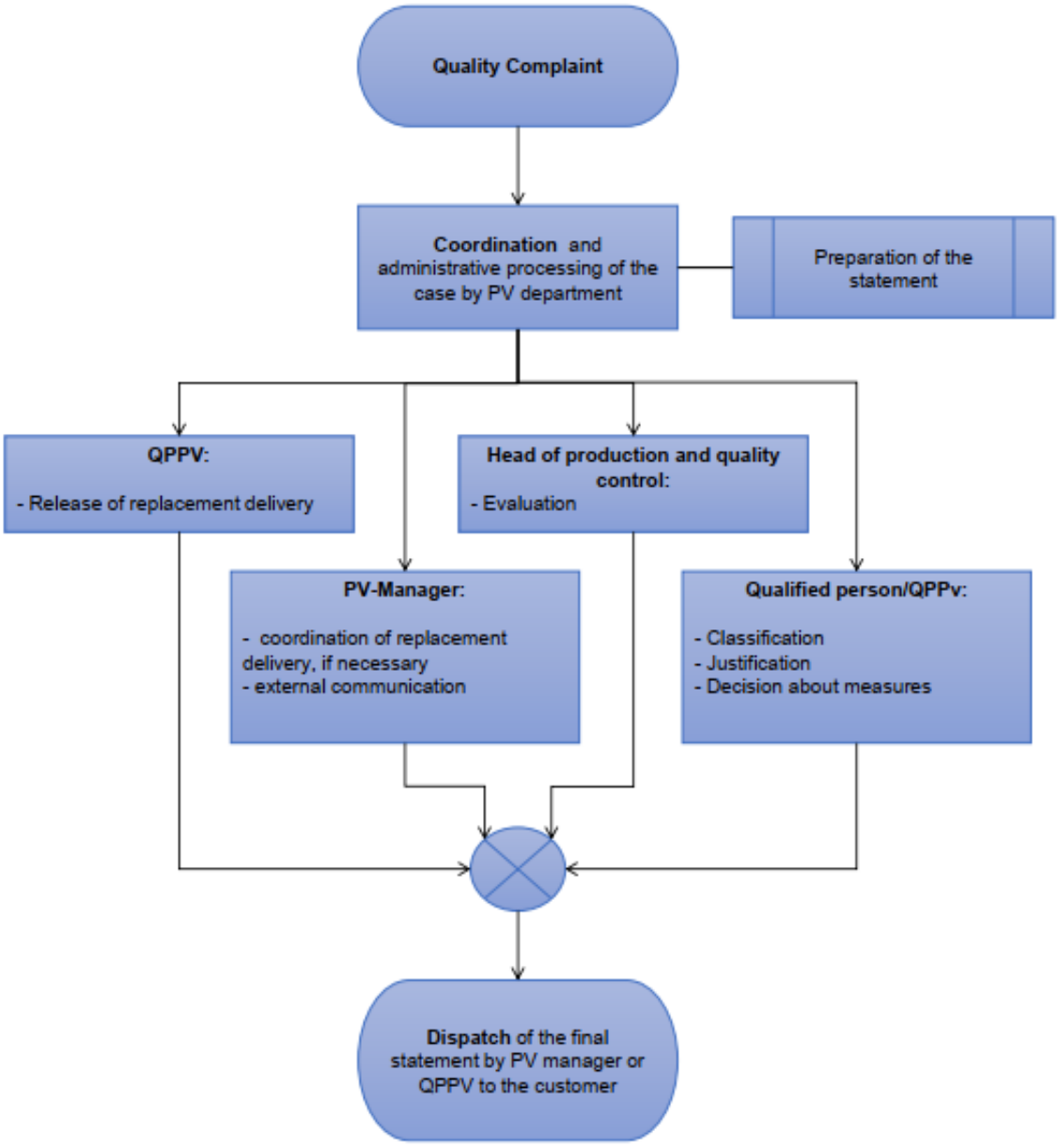

Figure 2: Flowchart for the processing of complaints

Under the concept of Critical Process Attributes (CPAs) mentioned in chapter 2, the following section of this thesis elaborated on the various influencing factors that led to a delay in the processing of complaints and sending response letters to the customer.

2. Research Questions and Objectives

The present research was done in the field of pharmacovigilance in 8 months during the internship in a pharmaceutical company named AqVida GmbH. Focusing on the complaint management system, the core objective of the proposed study is to examine the following questions:

- *What are the Critical Process Attributes (CPAs) in complaint handling? How do they impact the process in the company?*
- *What are the current problems in the processing and the evaluation of the complaints?*
- *How can the complaint management system in the company be improved?*

General Objective:

The general objective of this study is to analyse the means via which processes and the structure of the complaint management system in the pharmaceutical company may be optimised.

Specific Objectives:

- To identify and highlight the issues causing the delay of the response to the customer, and to present ideas for better and fast analysis of the complaint management system of the company
- To introduce a fast system of response to the complaints that could have a positive impact on the customer

3. Method

The following chapter outlines the applied research design that was chosen to examine the research questions. In the beginning, the qualitative method as an appropriate method for this study is discussed. Following that, a document analysis procedure and a developed interview guideline as data collection instruments are described. The data collection procedures, which are implemented in this study such as focus groups and in-depth interviews are also presented. Subsequently, the data analysis strategies used during the research process will be illustrated.

3.1. Qualitative Approach

To answer the research questions, qualitative study methodology was chosen as it helps in exploring, understanding, describing, and identifying various concerns within the phenomenon of interest (Ritchie, Lewis, Nicholls & Ormston, 2014, p. 51). According to Creswell (2013), qualitative research is appropriate to use when there is a need for a detailed understanding of the issues which cannot be observed directly (Creswell, 2013, p. 65).

The qualitative approach including research methods like dedicated group discussion and detailed interviews, etc. permits the examination of the experiences of the people. It helps in identifying the issues by the stance of candidates of the study for a comprehensive understanding of elucidation and explanation given by them about the behaviour, objects, or events (Hennik, Hutter & Bailey, 2010, P. 08). Hence, it is a method that can be helpful to understand the knowledge and the behaviour of individuals who experience the problems (Flick, 2016, p. 28; Creswell, 2013, p. 44). The following table illustrates the main features of qualitative research, which shows its objectives and purpose. It also includes the data collection method, data analysis and outcome.

Table 2: Main features of qualitative research

Objectives	To gain a detailed understanding of underlying reasons, beliefs, motivation
Purpose	To understand why, how? What is the process? What are the influences or contexts?
Data	Data are words (textual data)
Study population	The small number of participants or interviewees Selected purposively (non-randomly)
Data collection	In-depth interviews, observation, group discussion
Analysis	Analysis is interpretive
Outcome	To develop an initial understanding to identify and explain behaviour, beliefs, or actions

(Source: Hennik, Hutter & Bailey, 2011, p. 16)

While planning the qualitative research, along with these features mentioned in Table 2, it is also important to foresee the possible ethical issues that might emerge during several phases of the research process such as in the very beginning, during data collection, analysis, in reporting, and publishing of the study (Creswell, 2013, p. 56-57). "These include anonymity, confidentially, informed consent, researchers' potential impact on the participants and vice versa" (Sanjari, Bahramnezhad, Fomani, Shoghi & Cheraghi, 2014).

Within qualitative research, there are many different approaches, namely: Phenomenology, ethnography, grounded theory, and case study (Creswell, 2013, p. 104). The description and examples of the above-mentioned research designs are mentioned in the following table.

Table 3: Qualitative research designs

Research design	**Definition**	**Examples**
Phenomenology	To derive an understanding of essential meanings as constructed through interpretation of people's lived experiences	– In-depth interviews – The small number of participants
Ethnography	To develop a deep understanding of complex social and/or cultural phenomena within specific settings or groups, by direct interaction and engagement	– Researcher's own experience, perspectives, and interpretations – Data collection must take place over an extended period
Grounded theory	To evolve a new theoretical model/process of the desired interest, based on reviews and experience of the research participants	– Data collection involves interviews with participants who are selected using theoretical sampling – The stepwise process between data collection and analysis to develop and elaborate on the new process emerging from the analysis
Case study	A holistic approach by analysing persons, events, decisions, periods, projects, policies, and institutions	– Single case study including a single setting or group – Multiple case studies comparing different setting groups – Triangulation for case studies including multiple data sources

(Source: Astalin, 2013, p. 119-122)

Among these approaches, this research follows the grounded theory approach since grounded theory enables us to study multiple individuals involved in an action, process, or interaction (Creswell, 2007, p. 78-79).

For the ease of researchers in collecting data for qualitative research, four different techniques were proposed by Creswell (2007) which are observations, field work, interviews (including individual and group interviews), and document analysis. Hence, either of these techniques can be followed by researchers for the data collection especially in a grounded theory approach (Creswell, 2007).

Despite the data collection by observations and interviews in most of the grounded theory studies, documents can also help in conducting these studies. "Pandit (1996) conducted one such study, using existing literature and documents to create two case-study databases from which a grounded theory of corporate turnaround was generated. The documents took the form of reports in the newspaper, trade journals, business journals, company documents and press releases" (Bowen, 2009, p. 34).

The researcher in this study used document analysis in conjunction with interviews as a source of data collection by applying the grounded theory approach. The purpose of using a grounded theory in this study was to better understand and investigate the antecedents and factors associated with the phenomenon of complaint handling as perceived by employees.

3.1.1. Document Analysis

The first data collection tool used in this research is document analysis as a qualitative research method. In recent years, there has been an increase in the number of research reports and journal articles that mention document analysis as part of the methodology (Frey, 2018; Bowen, 2009, p. 28). Documents required for systematic evaluation, as part of a research, take a diverse range of forms that may include advertisements, application forms, background papers, meeting minutes, registrations, reports, summaries, survey data, etc. The complaint forms (complaint acceptance and complaint processing forms) of the company AqVida GmbH, an overview table of complaints over the past five years, and reports/statements issued to customers in response to complaints were all taken into account in this research study. The information gathered from these documents was evaluated and analysed to extract background information, obtain a better grasp of the processing issues, and get insight into the study problem.

Document analysis is frequently used in conjunction with other qualitative research methods as part of triangulation, the use of distinct approaches to investigate the same phenomena within a study. The qualitative researcher is supposed to draw upon sources of evidence (at least two), i.e., to seek convergence and corroboration through various data sources and methodologies. Apart from documents, such sources include interviews, participant or non-participant observation, and physical artefacts (Bowen, 2009, p. 29). As a second source of evidence, the researcher in this study used open-ended, semi-structured interviews, which are discussed in the following section.

3.1.2. Development of Interview Guidelines

A semi-structured interview guide was developed as a second data gathering tool, and it will be used to conduct focus groups and face-to-face interviews. The interview guideline contains open-ended questionnaires as it helps in investigating topics from the participant's perspective (Creswell, 2013, p. 52). An open-ended question gives participants more options for responding whereas a close-ended question provides a pre-set response and may force participants to answer in a particular way (Creswell, 2012). The researcher was able to construct interview questions using the data obtained from the document analysis since this information suggested specific questions that needed to be answered. Some tips and tools for interview question types and proper placement given by Tracy in the literature were also considered when establishing the interview guide, as indicated in Table 4 below (Tracy, 2013, p. 146).

There are four basic types of questions based on the interview flow: opening questions, generative questions, directive questions, and closing questions. The interview can begin with informed consent and a question about the complaint-handling experience of the participants. Later on, questions about timelines are added. The directive questions, such as closed-ended questions regarding their tasks and typology, are followed next, which serve to arrange the participants' knowledge into distinct types or categories. The closing questions, such as demographic queries and suggestions, follow as a conclusion (Tracy, 2013, p. 146).

Table 4: Interview question types

Opening Questions	Generative Questions	Directive Questions	Closing Questions
Informed consent Rapport building Experience Factual issues	Tour Example Timeline Hypothetical Behaviour/action Posing the ideal Compare/contrast Motives/other's motives Future/prediction	Closed-ended Typology Elicitation Data referencing In vivo language Member reflections Devil's advocate Potentially threatening	Catch-all Identity enhancing Demographic Preferred pseudonym

(Source: Tracy, 2013, p. 146)

The interview guide of this study was comprised of 10 semi-structured and open-ended questions. The open-ended questions allowed the interviewees to open and discuss freely their thoughts and experiences (Creswell, 2013, p. 164; Flick, 2016, p. 221f.). Furthermore, the sequence of the interview questions was taken into consideration. General questions, which were less sensitive, were put at the beginning of the interview so that the participants did not feel uncomfortable. Hence, the first question focused on the interviewee's general background and complaint-handling experience. Secondly, directive questions regarding current concerns and issues were asked. Some questions also consisted of sub-questions. There were additional satisfaction and feedback questions at the end of the interview, where participants could express their opinions and suggestions for improving the system. For easy understanding, the questions were formulated in a possible simple and clear way. While phrasing questions, the use of acronyms-, and abbreviations were also avoided (Tracy, 2013, p. 144).

The developed interview guideline is shown in *Appendix C: Project Information and Interview Guidelines*. The interview questions are divided into the following five main themes.

- Background information and experience
- The main role in the complaint handling

- Current situation and satisfaction from the current system
- Training/workshop
- Feedback/suggestions

Pre-test:

The interview questions from the interview guide had to be reviewed and tested before conducting the interviews. Many experts recommend conducting a pilot test to refine the interview questions and develop appropriate lines of the query (Creswell, 2013, p. 165). Pilot testing also ensures that the right terminology and sequence are used. Two sample face-to-face interviews with a questionnaire were conducted to assess the time frame, comprehensibility, order, meaning, and simplicity of the questions. One PV manager participated in the pre-test to ensure that the questions were understandable, organised, and simple. Similarly, the time frame and the comprehensibility of the questions were also checked during the pre-test. The sequence of certain questions was modified after the pre-test. Some questions were rewritten in a more simple and unbiased manner, redundant questions were omitted, and two questions were merged into one. Following the pre-test, some technical terms were replaced with a more common language, and two new questions were added to the questionnaire. Appendix C contains the revised and reorganised interview guide.

3.2. Data Collection

A qualitative study data collection is the process of gathering data, which involves several interrelated activities such as getting permission, developing a good sampling strategy, and preparing equipment for digital and paper recording. Instead of depending on a single data source, the researcher might integrate two or more methodologies (Creswell, 2013, p. 44). For this study, the complaint records were analysed to determine the issues with complaint processing, and semi-structured interviews were performed to determine the cause of the issues from the perspective of the participants.

3.2.1. Data from Document Analysis

Relevant data on complaints from 2015 to 2020 were gathered from documents such as complaint forms, complaint overview tables, and reports/statements sent to the customer. The researcher reviewed a total of 98 complaint forms, 104 reports/statements for the customers, and 6 complaint overview tables for above mentioned time span. The data from these

documents were collected and coded in an excel file for analysis using Mayring's content analysis approach, which is described in section 3.3.2 Content Analysis.

3.2.2. Data from Interviews

According to Canvana *et al.*, the employees can be approached after or during office hours for data collection. The respondents should be assured that the data and results will be kept private and confidential. The type of interviews can range from structured, semi-structured, face-to-face, telephonic, one-on-one, computer-assisted interviews, group interviews, and focus group interviews, etc. (Cavana *et al.*, 2001, p. 138). Face-to-face, in-depth, open-ended, semi-structured, and focus group interviews can be conducted while using a "grounded theory" approach. In these types of interviews, the researcher has a better chance of getting detailed information on the beliefs, perspectives, and experiences of the interviewees (Polit & Beck, 2008).

Sampling and Recruitment:

According to Tracy, sampling is an essential step in selecting persons for study as research data sources. This is not just about finding individuals who want to talk about the issue, but also about finding individuals who are willing to donate their time and share their experiences and concerns (Tracy, 2013, p. 134). This study used purposeful sampling, which means that the participants were chosen in such a manner that they were able to actively contribute to a better knowledge of the research topic and to fit within the constraints of the research questions, aims, and objectives (Creswell, 2013, p. 156; Tracy, 2013, p. 134). The employees in the company who are actively involved in complaint management are the target group in this study. The first email was sent by the QPPV to employees who are directly or indirectly involved in complaint handling to notify them about the research project and invite them to participate in the interviews. Following that, individual communication was established by the researcher through email/phone, and appointments were set up. The participants received project information and the structure of the interview guide one day before the interview, which included the goal of the study and the method to be used in data collection (*see Appendix C*). The first two interviews were conducted in person at the company. Due to the pandemic situation, it was no longer possible to conduct face-to-face interviews, and most of the participants were switched entirely to the home office. As a result, the remaining interviews (five individual interviews and one focus group) were mainly done online via the video communication platforms Microsoft Teams (MS Teams) and Skype.

3.2.2.1. Focus Group

The focus group was conducted by grouping two PV managers because of similar tasks in complaint handling. The interview was conducted online using MS Teams, which was also utilised to record the entire conversation. The participants were first welcomed warmly before informing them about the overall research goal as well as the specific project objectives. The generated interview guide was used to conduct the focus group. It was also ensured that both participants had an equal chance to discuss their thoughts and experiences. They were not obligated to respond to all the questions if they did not wish to. Both participants were appreciated for their time and effort at the end.

3.2.2.2. Face-to-Face & Online Interviews

Two face-to-face interviews and five online interviews were held at the company. As for the focus group, the setting and required equipment for conducting other interviews were prepared beforehand. For online interviews internet connection was checked and recording was tested. Participants were initially welcomed and thanked for taking their time for the interviews. All the interviews began with a briefing that included a summary of the interview's goal, the amount of time it was going to take to complete, and how the results were to be used. The participants were open and willing to discuss their experiences throughout the interview. To facilitate an honest and interesting dialogue, the researcher also tried to construct a logistically possible and pleasant interaction. Interviewees were acknowledged for their time and for sharing their experiences and ideas at the end of the interview.

Interview Setting:

The meeting room of the company in Hamburg was selected as the interview location. Initially, all face-to-face interviews were scheduled to be conducted with employees in Hamburg, except for those working at Dassow and the QP, who is an external person and therefore most of the time not physically present in Hamburg. There were practically no interruptions throughout any of the interviews. During online interviews, there were several technical difficulties. A PV manager was present in most of the interviews, in addition to the researcher and interviewee, to

observe and support the researcher. The interviews took place at various times throughout the day, with some taking place in the morning and others in the afternoon.

3.3. Data Analysis

The data analysis in the qualitative study involved several steps like organising the data, conducting a preliminary read-through of the database, coding and organising themes, representing the data, and lastly forming an interpretation of them. Before that, the audio recorded data were transcribed. Finally, it involved representation of the data in the form of a discussion, table, charts, and figures among other things. These were the essential parts of qualitative data analysis which will be explored in the following paragraphs (Creswell, 2013, p. 179-180).

3.3.1. Transcription

The first step of data analysis for the interviews is to organise the data, which means the audio recorded interviews and focus group are organised in computer files and transcribed, which is one of the most important parts of transforming embodied interviews into usable data (Tracy, 2013, p. 177). There are numerous transcription rules in qualitative research such as transcription according to Ralf Bohnsack, Udo Kuckartz, etc. (Fuß & Karbach, 2014, p. 27).

In this study, the collected data was transcribed according to Kuckartz using MAXQDA software. This implies that every spoken word was transcribed precisely, but not transmitted in a summary form. The dialects of the participants were not transcribed but translated as precisely as possible into general language. If there were long breaks in between the interview, they were marked by mentioning brackets, which include dots (…). Incomprehensible words were identified by (unv.), the abbreviation of the German word “unverständlich” meaning incomprehensible. Also, individual pronunciation or vocalisation such as “Mhm, Na” etc. are not indicated in the transcript. The vocal expression of the interviewee supporting the statement like smiles or laughter are also documented in brackets. The names of other employees and other companies are not mentioned in the transcript. Any interruptions to the interview are also mentioned in brackets, along with the cause (phone ringing, internet problem, etc.). Incomplete sentences, incorrect syntax, and other errors are fixed without affecting the content. While transcribing, the original meaning, intent, and thoughts of the interviewee were reflected (Fuß & Karbach, 2014, p. 28). To maintain anonymity, each interviewee was assigned a number, such as B1, B2, B3, etc., which is mentioned in the results. The interviews were carried out in

English. After the completion of the research, all recorded interviews will be deleted, and the transcript texts will not be utilised for other purposes.

3.3.2. Content Analysis

There are many qualitative content analysis strategies for analysing the verbal data (Bortz & Döring, 2006, p. 31). The current study follows Mayring's traditional qualitative content analysis methodologies, which focus on the formation of the category (Diekmann 2006, p. 481). The system of categories is the core and essential tool of content analysis. These categories are understood as the operational definitions of variables (Kohlbacher, 2006, p. 10).

The data gathered in this study were evaluated inductively, moving from specific to general perspectives. These data-driven perspectives are given codes or categories of information, and then a label was assigned to them (Flick, 2006, p. 315). Meaningful text passages were selected and allocated to a category for this purpose. That section of text was marked and stored in another document simultaneously. This resulted in a large list of coded segments from which further classifications or themes emerged (Kuckartz, 1999, p. 90f.). The constant comparative approach was used throughout the coding process to compare the data relevant to each code and to adjust code definitions to match new data. This constant comparative method was circular, iterative, and reflexive (Tracy, 2013, p. 190).

To make sense of the data, the process of grouping the themes into larger units of abstraction follows the generation of themes or categories from the codes. This process is known as the categorisation process, and it aids in the understanding of data (Cresswell, 2013, p. 187). Thus, the researcher made thorough descriptions, themes, and interpretations based on their own or other people's opinions in the literature (Cresswell, 2013, p. 183). The last step in data analysis is presenting the information in the form of narratives, tables, charts, and figures, among other things.

3.3.2.1. Categories from Document Analysis

The data were coded after the researcher analysed the documents regarding complaints. The content of the complaint documents was first coded using three main categories: (1) total number of complaints, (2) reasons for complaints, and (3) complaints processing time. To create new categories, the data was frequently verified and rechecked. Document analysis aided in the refinement of concepts, identification of conceptual boundaries, and determination of the fit

and relevance of categories. After analysing the documents, the following categories and queries emerged.

Table 5: Main and sub-categories from document analysis

No.	Main Categories	Questions
1.	Total Number	– How many complaints did the company receive in the last six years?
2.	Reason	– What was the reason for these complaints?
3.	Processing time	– How much time did the company take for the processing of these complaints?
4.	Processing sequence	– What was the sequence of the processing and handling of complaints? – How many people were involved in the processing and evaluation of the complaint?
5.	Customer	– Who is the customer? – From which did customer the company receive most of the complaints?

(Source: Own representation)

3.3.2.2. Categories from Interviews

Before splitting the transcripts into various parts for content analysis, they were read numerous times to acquire a sense of the data and the interview. The next step was to describe, categorise, and analyse the data (Creswell, 2013, p.183-184). The categories in this study are based on the interview guideline and more particularly, the contents of the transcribed interviews (Flick, 2006, p. 315). The data analysis process in this research was purely inductive by which codes and themes were identified from the data and not from another theory. Following are the primary categories that emerged from the data analysis. The table below provides an overview of the main categories as well as their sub-themes.

Table 6: Main and sub-categories from interviews

No.	Main Categories	Sub-Categories
1.	Background & experience of participants in complaint handling	– Background information – Position in the company – Experience in the complaint handling
2.	Types/classification of complaints	– Quality complaints – Adverse drug reaction
3.	The main role in complaint handling	– Focus on main tasks in the company related to complain handling
4.	Current situation	– Current problems in handling tasks – Reasons for extended time required for the assessment
5	Critical attributes	– Influencing factors causing a delay in the processing of complaints
5.	Satisfaction	– Satisfaction level with the current system
6.	Training	– Training for performing own tasks
7.	Suggestions	– General suggestions for improving the system
8.	Expectations/wishes	– Expectations or wishes for the new system

(Source: Own representation)

According to Webster, Lewis, and Brown, the privacy and anonymity of participants should be respected, while sharing results (Webster, Lewis & Brown, 2014, p. 78). For a successful survey, anonymity is important to get the information from the participants by increasing their cooperation and ensuring them not to be revealed to others (Lavrakas, 2008). Therefore, while presenting their statements in the results, participants were assigned pseudonyms. There will also be no such information published which will potentially harm participants in the present or future.

4. Results

In this chapter, the results of analysed data from documents and interviews are presented.

4.1. Results of Document Analysis of Complaints

The data collected from document analysis from the year 2015 to 2020 are categorised and presented below. In the beginning, the total number of complaints is presented and then follows the information about the customer, reasons for complaints and their processing time. In the end, the processing sequence of complaints is presented.

4.1.1. Total Number of Complaints

The total number of complaints in the company from the year 2015 to 2020 is presented below.

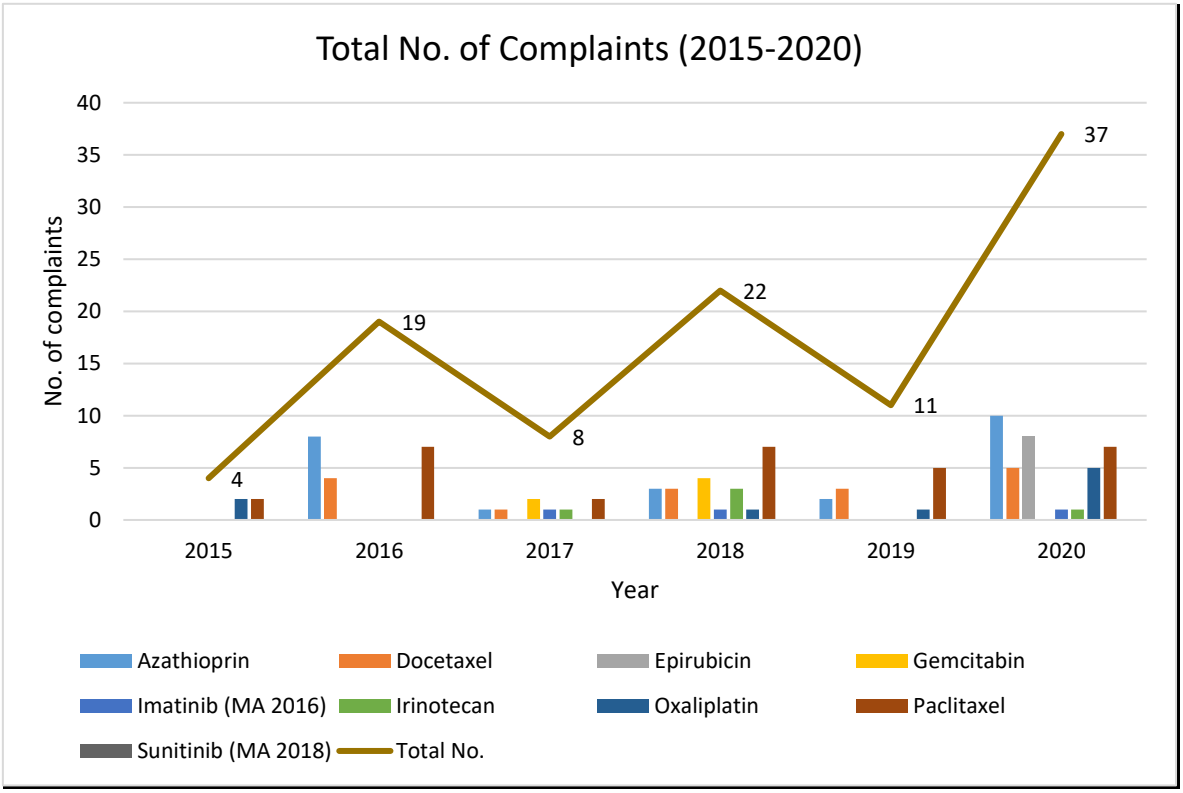

Figure 3: Total number of complaints – in brackets: year of initial MA during the analysis period

As shown in Figure 3, there is an irregular trend in the total number of complaints from the year 2015 to 2020. In the year 2015 AqVida received a total of 4 complaints concerning the products Oxaliplatin and Paclitaxel (2 complaints respectively). After that, the number of

complaints increased to 19 complaints in the year 2016. In this year, the company received complaints from the products Azathioprine (8 complaints), Docetaxel (4 complaints) and Paclitaxel (7 complaints). The number of complaints in 2017 decreased again to 8 complaints received from the products Gemcitabine (2 complaints), Azathioprine (1 complaint), Imatinib (1 complaint), Irinotecan (1 complaint), besides Docetaxel (1 complaint) and Paclitaxel (2 complaints). This trend was increased again in 2018, where the company received 22 complaints in total. The complaints in this year were almost from the same products as the complaints in 2017 but with an increased number. The company received complaints about Azathioprine (3 complaints), Docetaxel (3 complaints), Gemcitabine (4 complaints), Imatinib (1 complaint), Irinotecan (3 complaints), Oxaliplatin (1 complaint), and Paclitaxel (7 complaints). In 2019, there were 11 complaints in total for the products Docetaxel (2 complaints), Epirubicin (3 complaints), Oxaliplatin (1 complaint) and Paclitaxel (5 complaints). In 2020 AqVida received a total of 37 complaints, three times more than the number of complaints in 2019. The complaints were concerning the products Azathioprin (10 complaints), Docetaxel (5 complaints), Epirubicin (8 complaints), Imatinib (1 complaint), Irinotecan (1 complaint), Oxaliplatin (5 complaints) and Paclitaxel (7 complaints). It can also be seen in Figure 3 that the company received the marketing MA for two products Imatinib in 2016 and Sunitinib in 2018, that is why there were no complaints about Imatinib before 2016 and for Sunitinib before 2018.

4.1.2. Customers

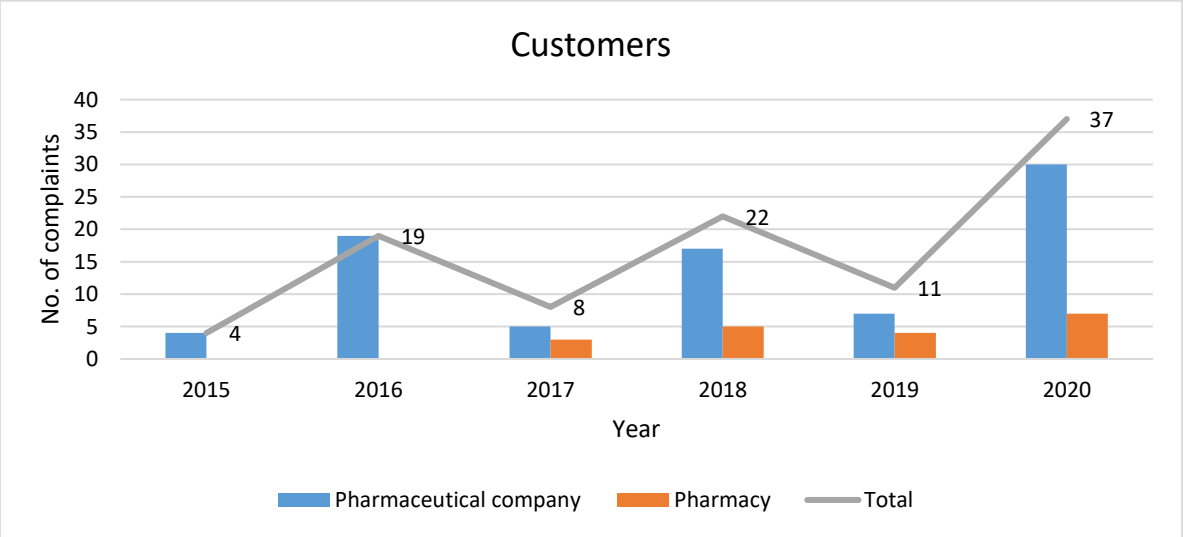

Figure 4: Customers

4. Results

The company received 30 complaints (81%) from pharmaceutical companies and 7 complaints (19%) from pharmacies in 2020. In 2019, 7 complaints (64%) from pharmaceutical companies and 4 complaints (36%) were received from pharmacies. Similarly, the number of complaints from pharmaceutical companies in 2018 was 17 (77%) and from pharmacies were 5 (23%). In 2017 only 5 complaints (63%) were received from pharmaceutical companies and 3 complaints (38%) were from pharmacies. All the complaints in 2016 and 2015 were received from pharmaceutical companies.

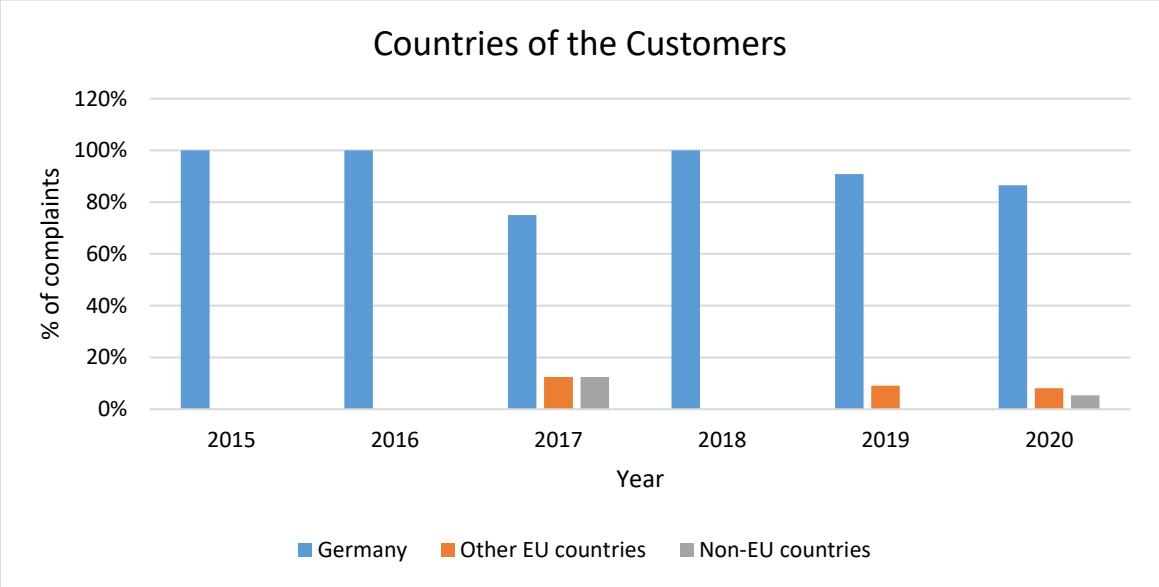

Figure 5: Countries of the customers

The company received all the complaints in 2015, 2016 and 2018 exclusively from customers in Germany. In 2017, 75% of complaints were received from Germany, and 13% complaints were received from other EU countries and 13% complaints were received from non-EU countries. 91% of complaints in 2019 were received from Germany and 9% from other EU countries. Similarly, 86% of complaints in 2020 were received from the customers in Germany, 8% complaints from other EU countries and 5% from the customers in non-EU countries.

4.1.3. Classification of Complaints

The complaints were also evaluated according to the classification specified by the European Commission mentioned in Table 1. The classification of complaints from the years 2019 and 2020 as presented below, was considered in the analysis.

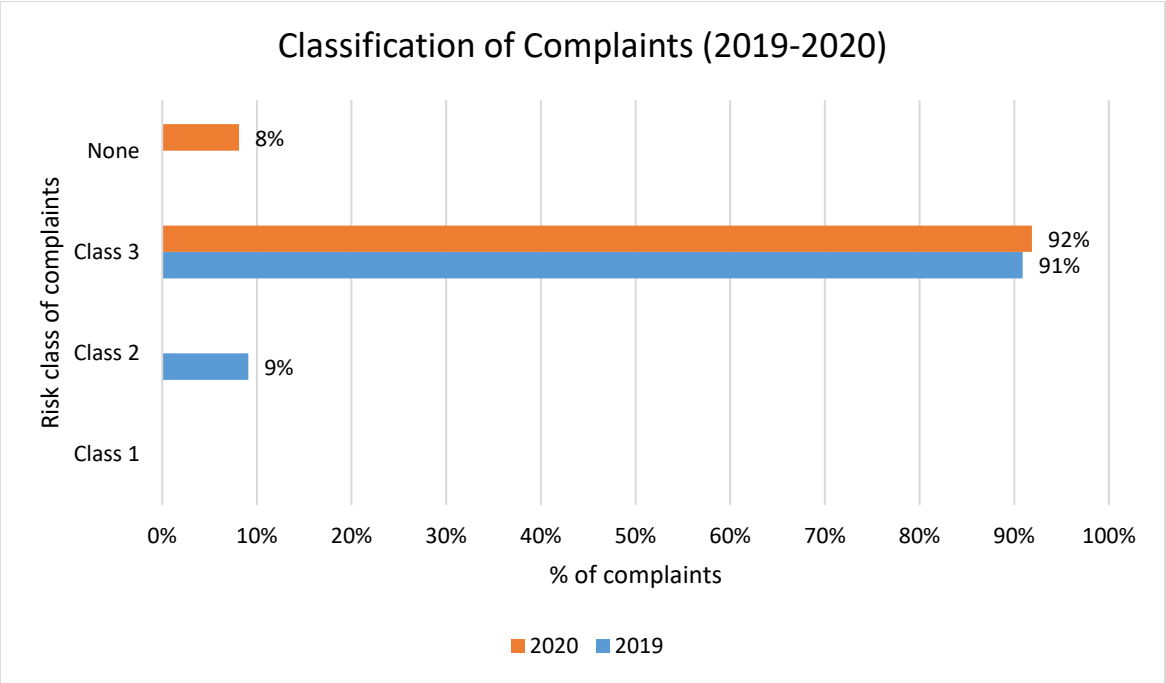

Figure 6: Classification of complaints

In 2019, 91% of complaints fall in the category of class 3 and 9% of complaints fall into class 2. In 2020, 92% of complaints fall into the category of class 3 and 8% of complaints were rejected and therefore not given any class.

4.1.4. Reasons of Complaints

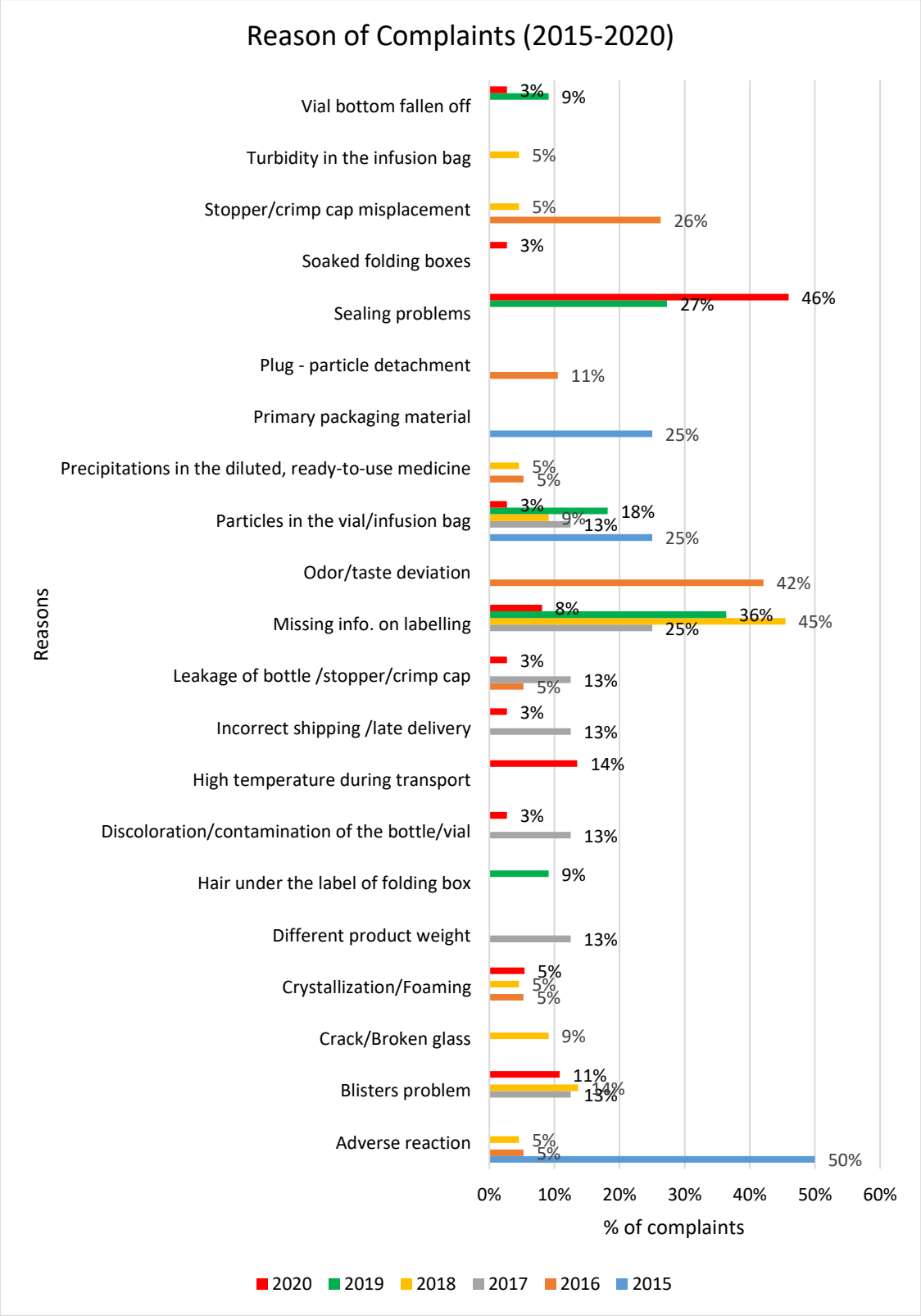

Figure 7: Reasons for complaints

4. Results

There were different reasons for complaints from the year 2015 to 2020. The company received more complaints about sealing problems in 2020 than in 2019 (46% vs 27%). High temperature during transport (14%) and problems with blisters (11%) were the other most common reasons for the complaints in 2020. It can be seen in Figure 7 that the sealing problems (27%) were also the most common reason in 2019 after missing information on labelling (36%). There were also more complaints about particles in the vial (18%) in 2019. The most common reason for complaints in 2018 was about missing information on the labelling (45%) and blister problems (14%). Similarly, the common reason for complaints in 2017 was again the missing information on labelling (25%). The company received most of the complaints about odour/taste deviation of the medicine (42%) in 2016 and about the adverse reaction (allergic reaction) (50%) in 2015.

4.1.5. Processing Time of Complaints

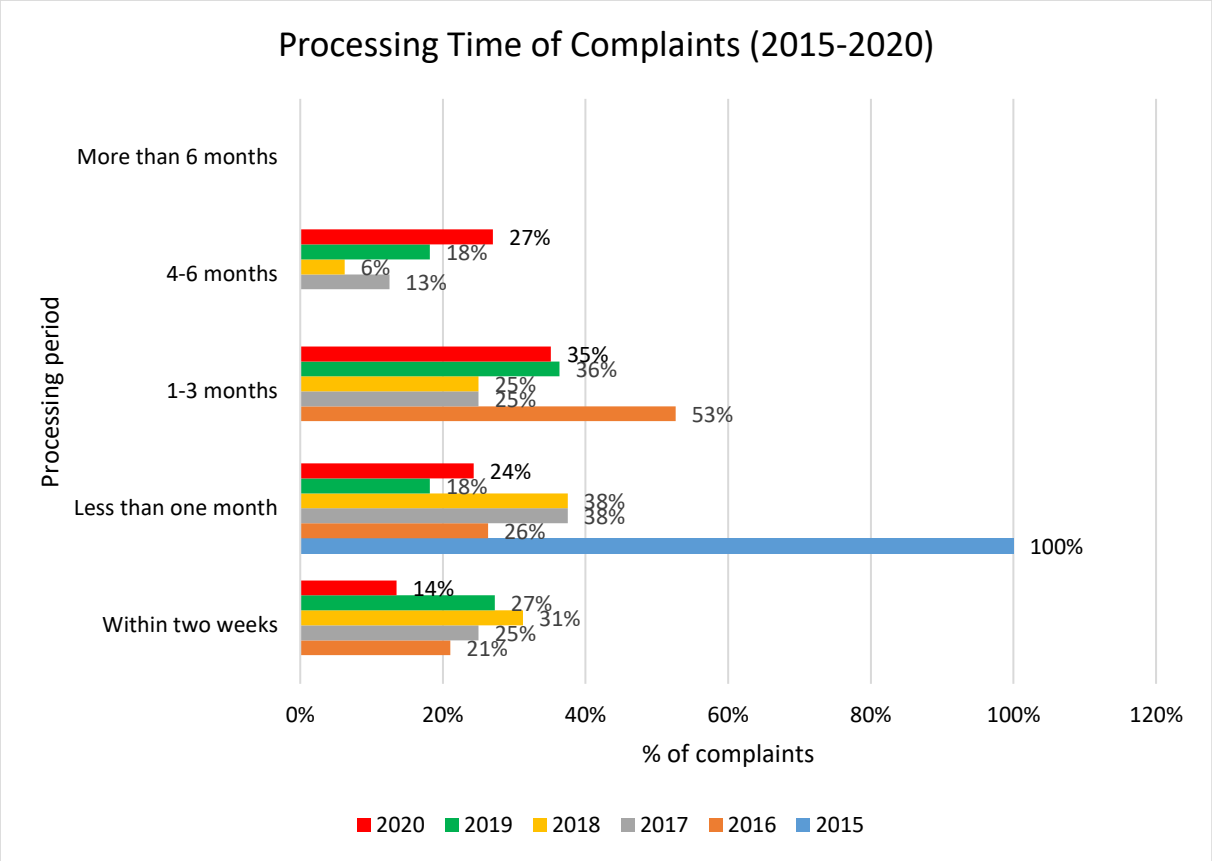

Figure 8: Processing time of complaints

As the processing time of complaints according to the SOP of AqVida is 10 working days, only 14% of complaints were processed in proper time in 2020. For practicality, the deadline is calculated as 2 weeks (including weekends), instead of 10 working days. 24% of

complaints took the processing time of less than 1 month. 35% of complaints took the time of 1-3 months, whereas 27% of complaints were processed between 4-6 months in 2020. In 2019, 27% of complaints were processed within 2 weeks and 36% of complaints took the processing time of 1-3 months. 31% complaints in 2018, 25% complaints in 2017 and 21% complaints in 2016 were handled in a proper time. 38% of complaints in 2018 and 2017 took less than 1 month to close. 53% of complaints in 2016 were handled between 1-3 months. All the complaints in 2015 took less than 1 month to close.

4.1.6. Processing Sequence of Complaints

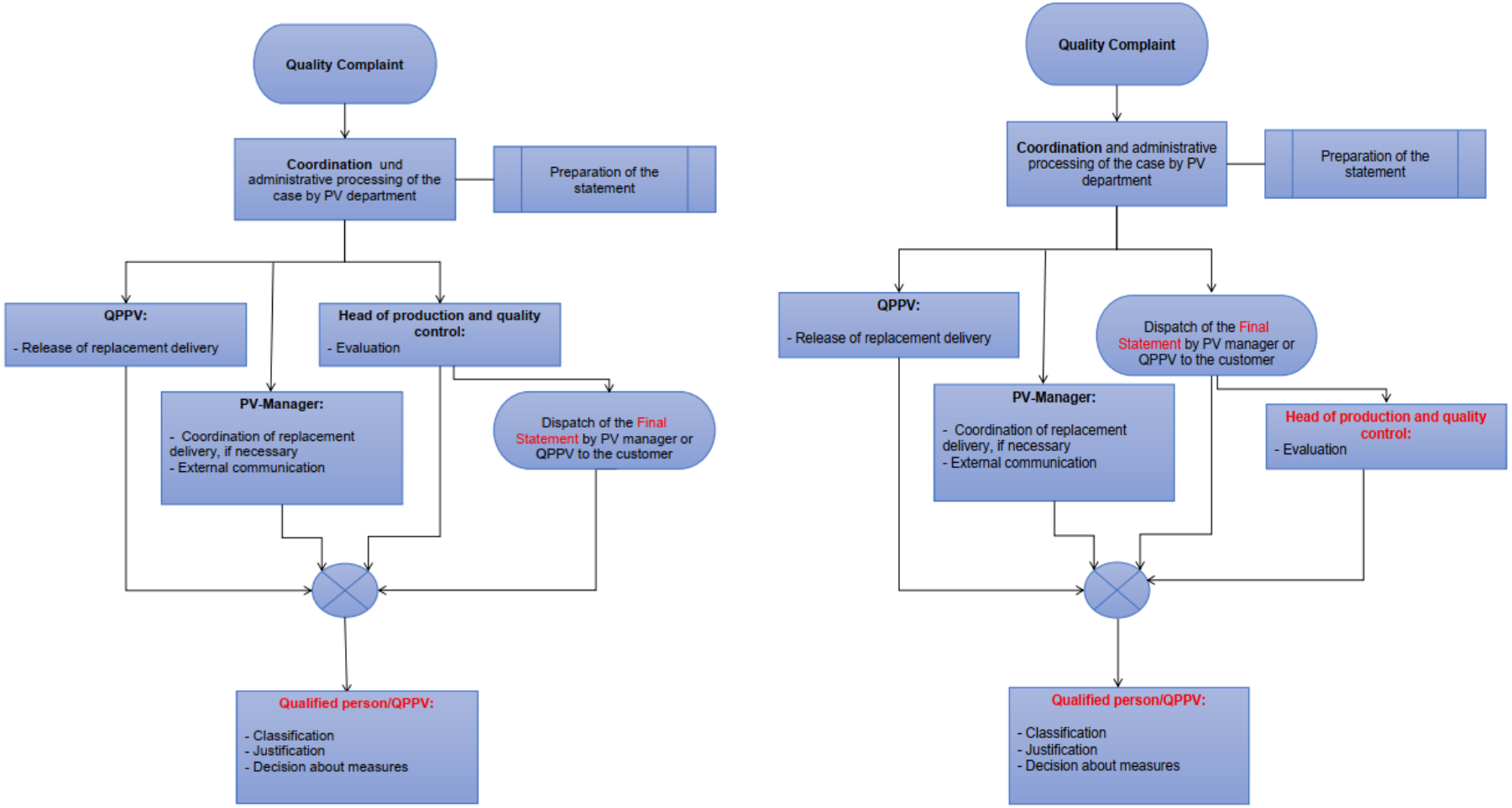

Figure 9: Processing sequence cases 1 & 2 in 2020

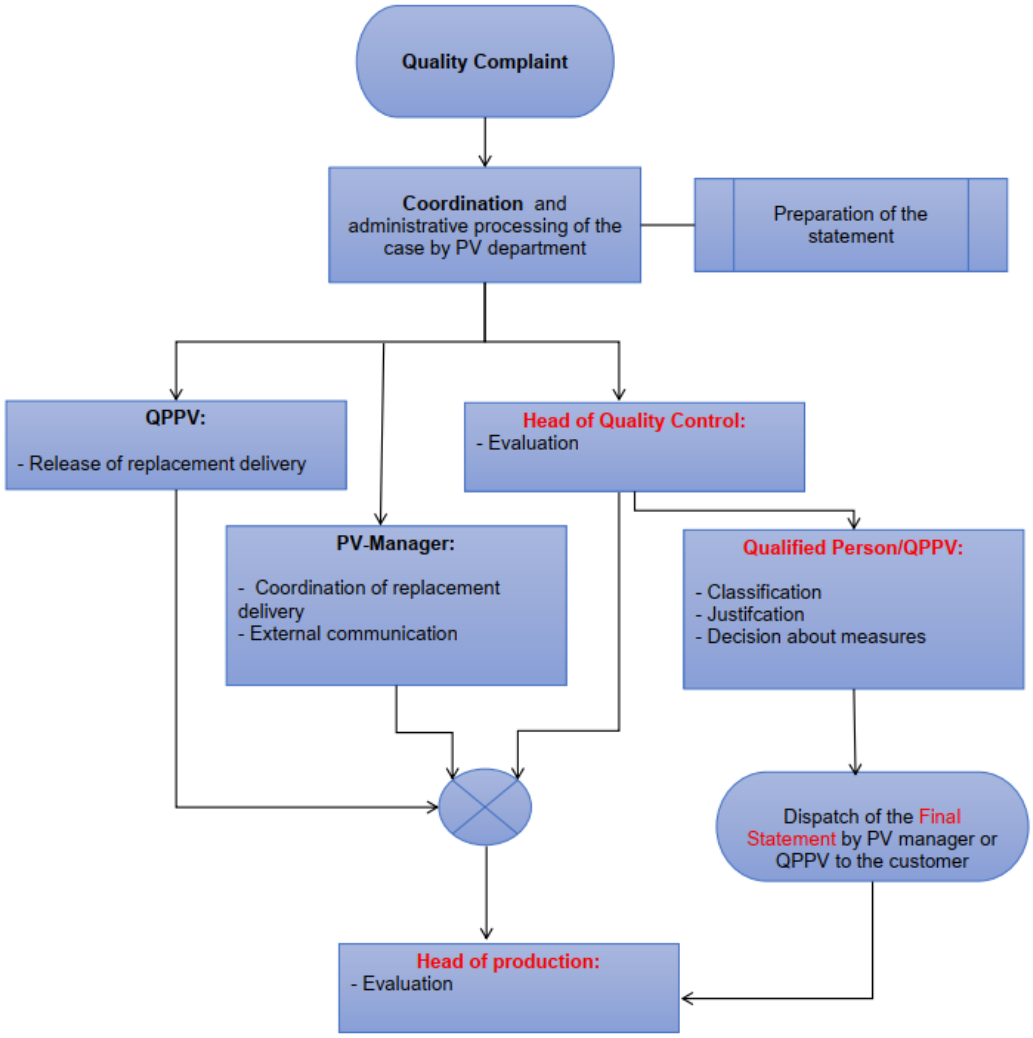

Figure 10: Processing sequence case 3 in 2020

Figure 9 and Figure 10 represent the processing sequence of complaints in 2020. In comparison with the flowchart presented in Figure 2 on page 10 , the sequence was not followed due to the long processing time of complaints as shown in Figure 8 on page 30.

4.2. Results of Interviews

In this section, the results of the analysed data from interviews are presented. Overall, eight main categories have emerged from the data analysis. At first, the participant characteristics are described in detail. Afterwards, the main categories and associated sub-themes are described comprehensively. Each category and the according themes will be described consistently with the participant's experiences and opinions which also includes the statements of the participants. The statement of participants helps in understanding the perception of current problems related to complaint handling.

The description of the main categories starts with the background information and experience of the participants. Afterwards, the main role of the participants in the complaint handling and the current situation and problems of the company related to the complaint management process is presented. Further on, the extent of satisfaction of the participants with the present system and information regarding training or workshops are presented. In the end, the expectations or wishes of the participants with the new process are presented.

4.2.1. Participants

Altogether nine people participated in this study. There were two participants in the focus group, two in a face-to-face interview and five in the online interview. Three participants in this study were female and six participants were male. All the interviews were conducted in English and the participants took part in the research process voluntarily.

Table 7: Sample characteristics of the study participants

No.	ID	Gender	Position in the company	Interview duration	Interview location
1	B1	Male	PV manager	48:00 min	Company
2	B2	Female	QPPV	36:00 min	Company
3	B3	Male	Head of production (Hamburg)	37:40 min	Online
4	B4	Female	PV manager	31:23 min	Online
5	B5	Female	PV manager	31:23 min	Online
6	B6	Male	Head of production (Dassow)	35:13 min	Online
7	B7	Male	General director of the company	29:43 min	Online
8	B8	Male	Head of Quality Control	44:48 min	Online
9	B9	Male	QP	44:58 min	Online

(Source: Own representation)

4.2.2. Experience in the Complaint Handling

The participants in this study shared different experiences in complaint handling from this company and their previous companies. The participants were asked, how long they have experience in complaint handling and if they have experience from the previous companies. If this was applicable, they were asked to compare the complaint handling process in their previous job with the process at AqVida. Five participants had experienced in complaint handling for less than ten years. One participant had an experience of fifteen years, and three participants had the experience of more than twenty years in general. Some participants said that the process at AqVida is more complicated than compared to the process in their previous companies. One participant said in this context:

„We have a complicated process, and many people are involved" (B6, Pos. 15).

When this participant was asked, if the complaint process in his previous company was the same as the process here at AqVida, he answered:

„No, it is quite different, it was a much easier and smoother process. We have an extremely heavy and complex process" (B6, Pos. 8).

Many participants also mentioned that the complaint process in their previous companies was handled by the QA department but at AqVida it is handled by the PV department.

„… the complaints process in my previous companies was always handled within the quality department, so I was never involved in complaints handling" (B6, Pos. 6).

One participant stated that:

„…In one company the complaint handling was organised by the Quality Assurance department and in the other company it was organised by the Regulatory Affairs department and here at AqVida, it is organised by the Pharmacovigilance department…" (B2, Pos. 12).

One other participant stated in this context:

„I think every company has a different scenario and different procedures. SOPs are a little bit different also, but in general, I guess, in the overview, it's quite similar...but at that time in other company it was QA, who was actually the main handling department" (B3, Pos. 12).

In this way, the participants shared their experience with the complaint handling from their previous companies and shared their views about the process here at AqVida.

4.2.3. Main Role in the Complaint Handling

The participants were asked about their main role in the complaint handling process at AqVida. Three PV managers said that they are responsible for coordinating the process regarding their products, as the products are assigned to the managers. One of the participants in the focus group stated that:

„…So, we are coordinating the process with regards to our products, so we are basically managing the filling out of the forms and coordinating with the other concerned parties regarding the input that we need from their sides, and the communication with, for example, the pharmacies, from which we received the complaint..." (B4, B5 (Focus Group), Pos. 16).

The head of production is responsible for investigating the product in terms of production-related defects. One of the heads of the production department stated:

„I am one of the reviewers or investigators in review and report writing for the complaint in terms of the production-related comments... "(B3, Pos. 14).

Similarly, the head of quality control is responsible to evaluate the complaint regarding quality-related defects. When he was asked about his main role in the complaint handling process, he answered:

„Yes, I fill the sheets for QC, so when we get a complaint from the market, at first, we check the reference samples, what is happened with the reference sample, if everything is fine with this sample, do we have the same problem in the reference sample as from the market for example. It means when we have a bad print for the batch number, you see the last complaint there was a bad print on the cartons from the variable data and I check right now in this reference sample, if there is also a bad print on the box, and in the most cases, there is not any bad print. Maybe this could happen during the production, we checked out cartons, normally we check all the cartons, but you know we are humans (smile), that is clear. These things could happen" (B8, Pos. 8).

4. Results

The QPPV is responsible for many tasks in the complaint handling process. She does the preliminary assessment of the complaint at the beginning and at the end, she has to finalise the complaint by classifying the complaint and send the final response letter to the customer together with the responsible PV manager and also other tasks which are mentioned below. The QPPV stated with regards to her tasks in the complaint handling process:

„I am the "Stufenplanbeauftragte", so my task is to evaluate in the first place when the complaints arrive, is it a quality complaint or is it an adverse event and also my task is to sign the "Stellungnahme" the statement together with the PV manager which is sent to the customers, to the person who sent us the complaint and also the third task is to finalise the complaint, its either me or the Qualified Person, often in the past it was only me because the Qualified Person is an external person, so it was easier for me to close the complaint because I am working in the company and my task there is that I have to classify the complaint according to the risk class and also make a short evaluation what are the reasons, as the complaint is new one or already known one. Yes, and in case of measurements, I have to decide which measurements result from the complaints" (B2, Pos. 20).

The QP was usually not involved in the complaint handling process since the responsibility of reviewing each case lay with one of QP and QPPV and the latter normally did this. The process was modified after a GMP inspection in November 2020 and the QP stated in this context:

„Until the inspection in Hamburg I thought, I do not have any role in that, because you know in my point of view, QPPV has the role. She has to check, and she has to answer. So, this is my opinion of the German Drug Law, but I do not know what exactly the inspector of the Hamburg authority said, if I only must be informed, informed is fine but at the moment somebody said I have to sign it, so at the moment I sign it. I am fine with signing it if it is not unusual what is written on the last page. But when I sign the form, on the first page nothing is filled out and I do not like to sign the form on the fourth page when the first page is not filled out" (B9, Pos. 10).

In the point of view of the QP, he is not the main responsible person for complaints. His main task is to release the batches and for the complaint handling, QA, QC, production and QPPV should be responsible for the evaluation and final decision of the complaint. He stated further:

„The problem was, I think I am normally out of the business because you know when I release the batches, it is fine and after this, if there are complaints normally production, QC and QA is involved and I think the final decision how to answer to the customer from my point of view should be done by the QPPV because she is the officer for graduated plans and she has to take care that the quality of the products on the market areas is defined. So, of course, I need to be informed about complaints because it can also be in the next batches or (…) or the root cause analysis shows that maybe we have a general problem and so I should take care while releasing the next batches. But I think the signature of mine is not necessary but ok you will see what at the end comes out of your new process" (B9, Pos. 10).

When the general director of the company was asked about his main role in the complaint handling, he answered:

„My main role is to keep all the strings together and to make sure that everyone receives the information from the other departments and of course, a lot of the historical technical background knowledge of the products and to put things in an overall context may be" (B7, Pos. 12).

In this way, all the participants explained their main roles in complaint handling at AqVida.

4.2.4. Reasons for Extended Time Requirement

The participants were asked specific individual questions regarding their tasks in complaint handling. The statistics from the analysis of the documents were shown to the participants and they were asked about the reason or circumstances which lead them to the extended time required for the assessment of complaints. Most of the participants said that the awareness of the importance of timely response was missing. Similarly in the participants' points of view, if there are too many complaints in the company, then it is difficult to remind everyone and every day of the processing and evaluation of complaints.

„In general, I think many things were going on and the awareness of the importance of a timely response may not have been there. I also think that there were problems with the reminder system, meaning that there isn't one, but if we had a way to automatically be reminded and also send a reminder to the other involved people that may be a useful thing" (B1, Pos. 40).

The QPPV was asked about the reason for sending a response letter to the customer before receiving the assessment from the production department or QA (*see Figure 10: Processing sequence case 3 in 2020*). As the assessment from QA or production came very late, the QPPV assessed the evaluation from them to send a response to the customer in a proper time. In this context she answered:

„… I think the reason there was that I was under pressure you can say because our SOP says that I have to inform the customer within 10 days that is one reason. And not only the customer, but this is also something you need to assess your complaint to check if there is a risk or there is no risk. So somebody has to make a decision, that's the other pressure I have as QPPV or "Stufenplanbeauftragte" and that's why I made a self-assessment, you can say that I assess myself and took the responsibility as QPPV and made a decision, ok, in this case, there is no risk I have an explanation, although I have not received fully assessment from manufacturing or Quality Control and that's why I have chosen the pragmatic way that I say okay for me it's more important to have fast information if there is a safety issue or not and that's why I assess by myself" (B2, Pos. 28).

As there are two heads of production in the company, it was sometimes not clear, who is responsible for which complaint. So, the information was sometimes not properly delivered

to them which was also one of the reasons for delayed responses. One of the participants said that if there is no clear responsibility assigned to the people there will always be miscommunication and information will not be transferred properly to the responsible person. The participant stated in this context:

„I would say it's a classic communication problem here, yeah. If there is no consent, who should work on the complaints and of course we are not always, I mean we are not the experts in the production department so we do not know who is now in this case the responsible person, I mean if this is defined more clearly to us then we will of course directly request the respective person to work on this complaint, but when it is not clear to us, it is not easy for us to address it to the right person, so ..."(B5 (Focus Group), Pos. 23).

The head of QA mentioned the problem of workload. As the heads of departments have a lot of responsibilities, they cannot always evaluate complaints immediately and in time. The head of QA stated:

„It's a workload of the people. You have seen in these complaints which we handled, that in the most cases, the heads of the departments are also on it. And in most cases, that we have a delay on it is because we do a lot of things in between and when the complaints are coming in, then we do not have time sometimes to answer directly on it, so later we forget it. Yes, we forget to answer it. So, that is what happened and then we have an SOP in place which said directly that we have to answer within two weeks, but we don't follow it" (B8, Pos. 10).

4.2.5. Current Problems in the Complaint Handling

The participants were also asked about the current situation and problems which they are facing right now in the complaint handling. Some of the important problems mentioned by the participants are presented below.

- Too low prioritisation and coordination in the departments
- No reminder system
- Little follow-up
- Few resources
- High workload
- Lack of timely detailed assessment from QA and manufacturing department
- Lack of specific investigators
- Lack of awareness of the importance of timely response of complaints
- No automatic digital system for handling complaints
- Missing written information during meetings or discussions
- Lack of process owner/specific manager for handling complaints

Besides these internal factors, the participants also mentioned that some external factors cause a delay in the assessment of the complaints. One of these external factors is the complaint sample which the customer should send back to the company for investigation and if the customer lives in overseas countries, it takes time until the sample arrives at the company. In this context one participant stated:

„ (…) sometimes the process is delayed because we need the samples from the customer so that we can analyse the product, e.g. when there are particles in the infusion bag or in the vials, we have to analyse it until we get the vials and we need to send them to the laboratory and it takes time" (B4 (Focus Group), Pos. 34).

4.2.6. Satisfaction with the Current System

The participants were asked to which extent they are satisfied with the current system of complaint management.

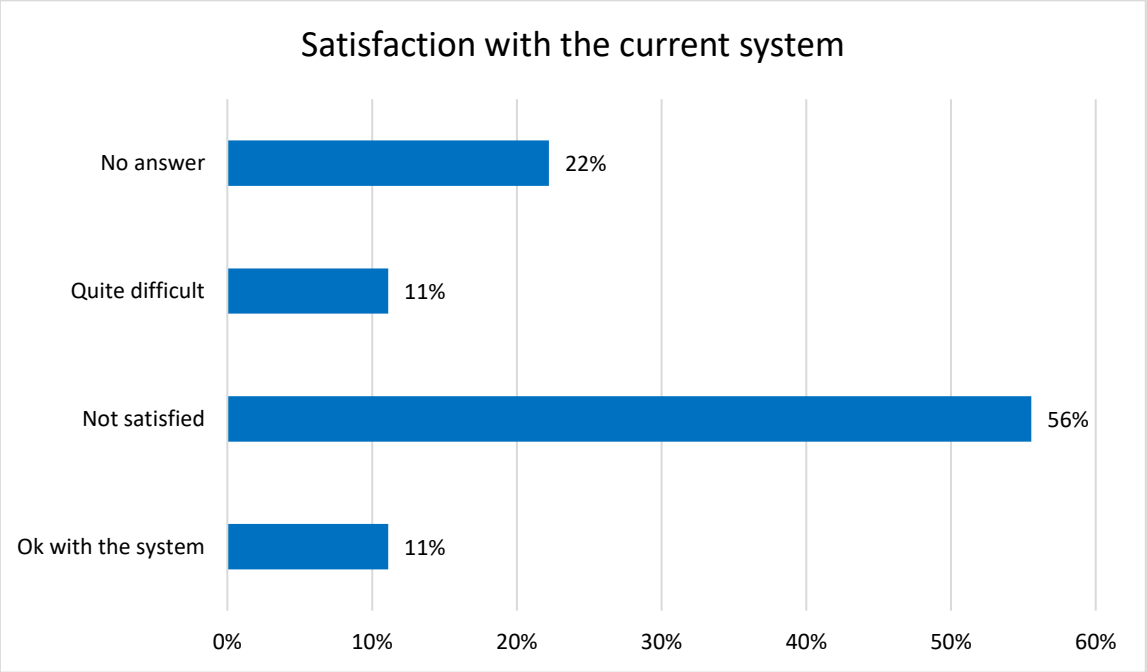

Figure 11: Satisfaction with the current system

11% of the participants said that they are ok with the system. One participant stated:

„I am okay, as long as we perform and everything is written on the form and the request samples and so on, then I think we should be okay. We have now a working system, I think. Of course, the distribution of the responsibility was still open, but I think now it is clear, so yeah, I think, the basic structure of the procedures and forms were okay" (B3, Pos. 62).

56% of participants were not satisfied with the current system. To the question of satisfaction level with the current system, one participant answered:

„Not at all "(B6, Pos. 36).

11% of the participants said that it is quite difficult to define the satisfaction level with the current system and 22% of the participants did not directly answer the question.

4.2.7. Training/Workshops

The participants were asked if they received any training or workshop for doing their tasks in complaint handling. As the SOP system of the company allows the heads of departments to read the SOP by themselves, so 63% of the participants are among the category of heads of departments. 25% of the participants stated to receive proper training in the complaint SOP. 13% of the participants complained that they did not get appropriate training regarding complaint handling. As a result, the training documentation of the participants and the content of the training were reviewed and discussed in the next chapter.

Figure 12: Training/Workshop

4.2.8. Suggestions for Improvement

The participants gave the following suggestions for the improvement of the complaint management system in the company.

- Automated reminder system instead of sending emails to the involved persons
- Time management
- Extended deadlines for processing of complaints

- To define clear responsibilities for each one of the persons involved in the complaint management
- More resources for complaint handling
- Clear overview on complaint status
- Template system for repetition of same complaints

Similarly, the participants mentioned that the complaint process should be easy. The focus should not be on having different forms to be filled out by different people, but rather the focus should be on two important points e.g., what is the impact of that complaint on the market and what should be done to prevent this complaint to happen again in the future. One participant stated in this context:

„I think we need to be quite objective, what is important in a complaint. In a complaint it is important to evaluate the impact of that complaint on the market and a complaint is important to understand what can be done not to happen again and these are the two things and the valuable things that satisfy, I don't want to say 100% but that may be 99% that satisfy that how do you address properly the complaint, so (...) we don't need to focus on having five or six different attachments then by five or six different people. We need to focus on two questions and our forms, and our process should be then around these two questions"(B6, Pos. 42).

5. Discussion

This chapter will summarise and discuss the study findings. The study methodology will also be discussed regarding the study design, the study population, and the interview schedule. Furthermore, the potential limitations of the study will be outlined.

5.1. Discussion of Results

The statistical data on complaint handling from the last six years showed that there was an irregular trend in the number of complaints from the year 2015 to 2020.

In 2015, the company received complaints exclusively about Paclitaxel regarding packaging material (one single case) and Oxaliplatin regarding allergic reactions. At that time, the company was not selling products under its own brand name and the medicinal products were manufactured at contract manufacturers, mainly located in foreign countries. The complaints were sent to the respective companies for thorough investigations. The resulting report of Paclitaxel stated that the batch was suitably produced on all the relevant standards and quality control. The manufacturer reviewed the master batch records and documents and did not find any specific deviation which could have impacted the product quality (Investigation report Paclitaxel, 2015). For the Oxaliplatin complaint concerning allergic reactions, the batch documentation was checked which did not show any abnormalities or deviations. The outcome of the assessment was that the allergic reaction is a common side effect of Oxaliplatin which is also described in the product information texts (Investigation report Oxaliplatin, 2021). This complaint was not related to a valid quality complaint, but a normally expected adverse reaction of the medicinal product.

In 2016, the company received a total of 19 complaints. From these 19 complaints, there were repeatedly 8 complaints (42%) about the same Azathioprine tablets regarding odour and taste deviations received from one customer. AqVida investigated the claimed batch and compared it with the old batches. However, a slight odour difference was detected from the QA department. According to the final assessment, this slight difference did not have a pharmaceutical significance (Investigation report Azathioprine, 2016). With regards to the taste of the complained product, a warning notice was added on the folding box of the finished drug product which stated that the Azathioprine film-coated tablets must not be

crushed but should be taken with liquid. Based on all investigations the quality of the medicinal product was not affected.

The second common reason for complaints in 2016 was about Paclitaxel and Docetaxel regarding stopper misplacement (26%). The customer complained that during the preparation of the infusion solution, the stopper was pressed into the bottle. The customer also sent pictures where a spike was used in the process. Spike is a needle that is used for injecting a medicine (Segen, 2002). The investigation report of the manufacturer showed that the medicinal product from the chemical point of view was acceptable and met all release specifications. However, according to the package instructions, piercing with a chemo pin or chemo spike must not be used because the rubber stopper of the vial may be damaged, resulting in loss of sterility (Investigation report Paclitaxel, 2017). Therefore, the customer was suggested to use a graduated syringe with a 21-G needle for product removal and to perform the piercing of the product at the lowest possible speed (Investigation report Docetaxel, 2016).

In 2017, the company received 8 complaints in total from 6 different products for various reasons (see section 4.1.1). Compared to 2016, there was no complaint regarding the change in smell or taste of Azathioprine tablets. 1 complaint was received again concerning stopper misplacement of Paclitaxel from another customer who was also advised to perform a proper piercing of the medicinal product.

In 2018, the company received a total of 22 complaints, more than the double number of complaints as compared to the complaints in 2017 (*see section 4.1.1*). Out of 22 complaints, 5 side effect cases of Gemcitabine and 3 cases of Docetaxel were reported. The Gemcitabine side effects were common adverse reactions mentioned in the package leaflet of medicine, so the quality defect was excluded in this complaint (Internal complaint investigation report Actavis, 2018). In the case of Docetaxel, as AqVida was not the MA holder for this product, the cases were reported from the responsible MA holder to the authorities. The most common reason for quality complaints in 2018 was the missing information on the labelling (45%). The complained vials were packed at other companies. The complaints were closed by AqVida, based on the improvement of the packaging control at those secondary packaging sites.

5. Discussion

In 2019, the company received a total of 11 complaints which were less than the number of complaints in 2018. The most common reason for complaints was again the missing information on the labelling (36%). These complained vials were packaged at the AqVida manufacturing site (secondary packaging site) in Dassow, Germany. After reviewing the respective batch manufacturing and packaging records, no deviation and no malfunctioning of equipment were identified. All processes were performed according to the written and approved instructions, which did not cause any risk to public health. However, during the secondary packaging process, the "unprinted" labels should have been detected and removed from the production. So, the company trained the operators for secondary packaging to double-check and detect such deficiencies. The second most common reason for having complaints in that year was the broken seals (27%). This happened with the implementation of Commission Delegated Regulation (EU) 2016/161 on 09.02.2019. The regulation was approved on 09.02.2016. In this regulation, it was stated that the seal labels and 2D barcodes must be applied to the packaging materials three years after the approval of this regulation (Regulations (EU), 2016/166). As the company has only been using the seal labels since February 2019, there was no complaint received about sealing problems before this year. The company received the first complaint about sealing in the last months of 2019. The more products with new sealing labels were brought into the market, the more complaints regarding defective seals were reported in 2020. The most common problems were the loose seal, constantly breakage or sticking of the seal sticker to the other packaging.

In 2020, the company received 37 complaints, more than the double number of complaints as compared to 2019. Unfortunately, as the reason described above, there was a steady increase in the number of complaints (47%) about sealing problems. The complained batches were packed at AqVida as well as at other contract manufacturing sites. AqVida and another concerned contract manufacturing site started working on finding and validating a new tamper-proof seal. Thus, the new improved seals with the lacquered free surface have been used since late August 2020. The second common reason for most complaints in 2020 was about high temperature during transport (14%) of Epirubicin (*see Figure 7*). The product was transported using Styrofoam boxes containing cold packs. These cold packs should be precooled for 24 hours at -20°C to ensure adequate cooling. However, cooling of the thermal pack was accidentally only performed at 2–8°C. AqVida tested the same product from a different batch, which was exposed to even harsher temperature conditions (exposure up to

23°C for up to 75 hours) at the end of its stability period. The results showed that the batch was still within the specifications. Thus, for this specific excursion, it was concluded that the product quality was most likely not affected.

From 2015 until 2017 AqVida received more complaints from pharmaceutical companies. There was a small number of complaints received from pharmacies because AqVida was not directly supplying the medicinal products to the pharmacies at that time. In 2018, AqVida started to supply medicinal products direct to the pharmacies under its brand name in Germany for the first time. From 2018 there were more complaints from pharmaceutical companies as well as pharmacies (*see Figure 4: Customer*). In 2015, 2016, and 2018 the company received all the complaints from Germany. In 2017, 13% of complaints were received from other EU countries and 13% from non-EU countries. Similarly, in 2020, only 8% of complaints were received from other EU countries and 5% from non-EU countries while 87% originated from Germany. The complaints were also categorised into three risk classes according to the classification characterised by European Commission mentioned in Table 1. The researcher analysed the classification of complaints from the years 2019 and 2020. It can be seen clearly in Figure 6 that 10 complaints (91%) out of total 11 complaints in 2019 and 34 complaints (92%) out of total 37 complaints in 2020 were given class 3 which means that these complaints did not cause any significant risk to the patient or public health and no external recall was required for these complaints. 1 complaint (9%) in 2019 was given a class 2 because this complaint could cause illness or mishandling of the medicinal product. Therefore, the affected batch was also blocked for sale. 3 complaints (8%) in 2020 were not given any class because no defect was detectable in these complaints.

The researcher also investigated the internal processing time of complaints. According to the present SOP of AqVida, the processing time of complaints is 10 working days, which was unfortunately not followed in the past years. It can be seen in Figure 8 that only 14% of complaints in 2020 were processed in time as compared to the processing time in the past years. Most of the complaints in 2020 took 1 to 3 months and even 4 to 6 months to complete the processing and evaluation. As the reason for delayed responses could not be analysed solely from the documentation of the complaints because there could be some current problems as well as some specific CPAs causing delays in the processing system.

5. Discussion

To find out these CPAs and current problems in the processing and evaluation, the interviews with the employees were conducted who are directly involved in the complaint handling. The participants shared different experiences from this company and their previous companies. Similarly, the current problems and different critical attributes causing delayed processing of complaints were also discussed. One of the CPAs in the complaint processing was the lack of connecting points of different departments in the complaint handling. The employees who are involved in the processing and evaluation of the complaints are the heads of the departments. As different departments from different locations are involved in the complaint handling, a follow-up was difficult with the increasing number of complaints which caused an inconsistent flow of information between different departments. Likewise, the complaints were easily forgotten or neglected due to the workload and lack of an automatic reminder system in the company. There was no complaint manager or software to reminds them to follow up on the due date for each person involved in the process.

The other important factor that caused a delay in the complaints process was also few resources or capacities in the departments. As there was no specific person for the investigations and for handling complaints, little follow-up was performed in the past years. The proper written information and protocols also play an important role in writing a good response letter for the customer. Sometimes the root causes of complaints and measures were only addressed in meetings and discussions, but not properly documented, which also led to a delay in sending the complaint report to the customer due to a lack of content about reasons and actions taken by the company to prevent this complaint in the future.

According to the interviewees, one of the reasons for delayed responses to the customer was also the lack of awareness of timely response of complaints to the customer. Most of the participants (56%) were not satisfied with the current complaint handling system due to a lack of proper management. 13% of the participants complained that they did not get appropriate training regarding complaint handling. As a result, the training documentation of the participants and the content of the training were reviewed and found that the content of the training presentation as well complaint SOP was written and explained exclusively in the German language. Many of the participants could not understand the German language and followed the complaint handling system. Every employee in the company must be trained on the very first day or after updating the complaint SOP. Because of this reason, the proposed SOP training presentation was formulated and held very general for the whole

company, which resulted in a lack of responsibility and awareness of proper and well-timed handling of complaints about the persons involved in the complaint management system.

An external factor mentioned by the participants as a reason for delayed responses to the customer was also to receive the complained sample from the customer for some specific investigations. Some analysis cannot be performed without a sample, and it normally took time until the company received a sample from the customer.

In addition to the above-mentioned CPAs, there were some current problems in the processing and evaluation of complaints. One of the dominant problems was the workload of the heads of departments due to the high number of complaints in 2020. This can be correlated with the increased production in that year. In the past there was a smaller number of complaints as the company was not producing the medicines under its brand name and the medicines were mostly sold to other pharmaceutical companies before labelling and packaging took place. At that time, it was easier to handle the complaints in time and to have an overview of repetitive complaints. Now, the company has its manufacturing site in Dassow Germany and selling its medicinal products not only to pharmaceutical companies but also direct to pharmacies. According to the internal production statistic of the company, the number of vials produced by AqVida in 2020 was 632 382, two times higher as they were in 2019 with 307 446 vials (Internal production statistic, 2019 & 2020). The enforcement of EU regulations regarding seal labels also played a significant role in the rising of defective seal related complaints. Too many complaints were not easy to handle in a short period causing difficulty for the upcoming complaints to proceed.

5.2. Discussion of the Method

For this research, the chosen qualitative approach was appropriate to explore the problems of the company regarding the complaint management system which helps to improve the system. Within the qualitative method, 1 focus group, 2 face-to-face, and 5 online interviews were conducted at different times. The interview with the employees helped to gain a detailed understanding of their problems in the processing and evaluation of the complaints. This type of data collection enabled the researcher to gain insight into the problems in a detailed form. Research has shown that, for optimum use of an interview time, an interview guide is needed to keep the researcher focused on the desired topic (DiCicco-Bloom & Crabtree, 2006). A semi-structured interview guideline with open-ended questions was used

during data collection, thereby enhancing the quality of the qualitative interviews. Open-ended questions enabled the researcher to identify related questions to the central questions asked in the interview guide. Apart from that, recording of the interviews eased data capturing, unlike handwritten notes, which are unreliable and might make the researcher miss the key points. Recording the interviews enabled the researcher to concentrate more on the content of the interview as well as the non-verbal cues (Jamshed, 2014).

In terms of analysing collected information, the systematic approach of the qualitative content analysis by Mayring (2014) was appropriate. The inductive approach of working through the transcripts, developing appropriate categories, and assigning relevant paraphrasers to the categories was suitable to explore the research question. However, the data analysis took a long time as the collected recording from interviews and focus groups had to be transcribed and saved on the computer.

5.3. Limitations of Study

As it was hard to get participants for this research, it could not work as planned. At first, it was planned to conduct all face-to-face interviews within the company. Because of the COVID-19 pandemic, it was hard to get appointments from the target group. At first, the face-to-face interviews were conducted in the company. After conducting two face-to-face interviews, it was not possible to conduct more interviews at the company because of some COVID-19 cases in the company. The employers were suggested to work from home. So, the rest of the interviews were conducted online via Skype and MS Teams.

The results of this study could be more representative if the study could include a large sample size. Altogether the researcher was able to interview 9 participants, which is a small size. Interviews with customers and/or health authorities would have contributed to get their point of view and satisfaction regarding the complaint management system of the company.

Another limitation could be the presence of a third person in the interviews. In most of the interviews, there was a PV manager besides researcher and interviewee for the observation, which on the one side was helpful for the researcher to be on the safe side that the interviewee is giving true information regarding issues or problems in the company, because the researcher is a new person and did not have information about the problems in the company. On the other hand, the presence of a third person from the company during interviews could

potentially cause bias, because it could happen that the interviewee did not share the exact problem or any negative information about the company in the presence of another colleague.

Lastly, the data transcription can never fully represent the interview situation, since it is impossible to transcribe all the elements of communications involved in an interview. A researcher has to leave out, include or transform certain aspects of a recorded speech (Dressing *et al.*, 2015, p. 22).

Hence, there were some limitations in the data collection and analysis procedure of this study. However, the interviews and focus groups with employees helped in gaining a depth understanding of the different perceptions of employees regarding the complaint management system in the company and their difficulties in processing and evaluating the complaints.

6. Strategies to Improve the Complaint Handling System

As the company is growing faster, the number of complaints will also be increased in the future. The limited awareness about the importance of timely response to the customer and extended time requirement for the processing and evaluation signifies that there is a need for a proper system for handling complaints. From the findings of this study, the company has the following basic problems in handling complaints:

- Process management problem
- Capacity/resources problem

Some of the strategies to tackle these problems and to improve the complaint handling system in the PV department are explained in the following sections.

6.1. Recommendations for the Process Management

A process of handling complaints should be reorganised in such a way that it comprises all important information and important investigation persons but in a simple way. To make the complaint process less complicated and thus faster, the following recommendations can be followed:

- One form instead of two separate complaint forms
- One complaint manager should be responsible for handling all complaints
- Preliminary assessment through responsible complaint manager instead of QPPV
- One specific person for investigation of the complaint in the QA department, instead of the head of the department
- One specific person for evaluation and assessment in the production department, instead of two heads of departments
- Risk classification and summarization of the main reason of complaint through the responsible complaint manager instead of QPPV/QP
- Sending complaint form to the customer instead of a specific complaint response letter
- Automatic reminder system for follow-up
- Sending complaints statistics every six months to all the persons involved in the complaint management process to give an overview of the status of complaints

- Extended time requirement or delay in the assessment of complaint from QA or manufacturing department with a written explanation in the case complained samples are required for specific investigations
- Notification to the customer in case of delay of more than 10 working days in the processing of the complaint
- Regular meetings and training to discuss the measures taken to reduce the number of complaints in the future and to improve public health and safety regarding the use of medicines
- Bilingual (German and English) update of SOP

These recommendations can be followed to reorganise a new complaint process. Firstly, there is a need for one PV/complaint manager who will be responsible for handling all the complaints. According to the EU-GMP Guide, a person should be designated responsible for handling the complaints and deciding the measures to be taken (European Union Guidelines to GMP, 2014). This person will be a contact person for all the departments involved in the processing and evaluation and will be responsible for the consistent flow of information through these departments. Secondly, there is a need for the application of a system in a company that will manage complaint handling, adverse event reporting, categorising complaints, and storing data in a retrievable form where all the involved persons can retrieve information that is only relevant to them. Combining the complaint management system with the technology is a very good strategy. This will involve reporting, processing, feedback, and follow-up through a computer system. This system can be web-based where complaints are directed to the QA and production department. This web-based system should be comprehensive enough to handle all report types and categorise them appropriately. The level of integration should be high so that the technology system records and keeps data in terms of product type and product profile. The system should also offer a database system to store all the data. The technology employed should have the capability to give any report requested by the personnel.

JobRouter®

"JobRouter® is a powerful and flexible low-code digitalisation platform. It helps companies to digitise and automate any business process. Users benefit from excellent process automation, agile document management, and efficient data management. It connects with existing systems to export, process, and archive or passes on data and documents and to

initiate new processes" (JobRouter AG, 2021). The following flow chart can be used to implement the process at JobRouter:

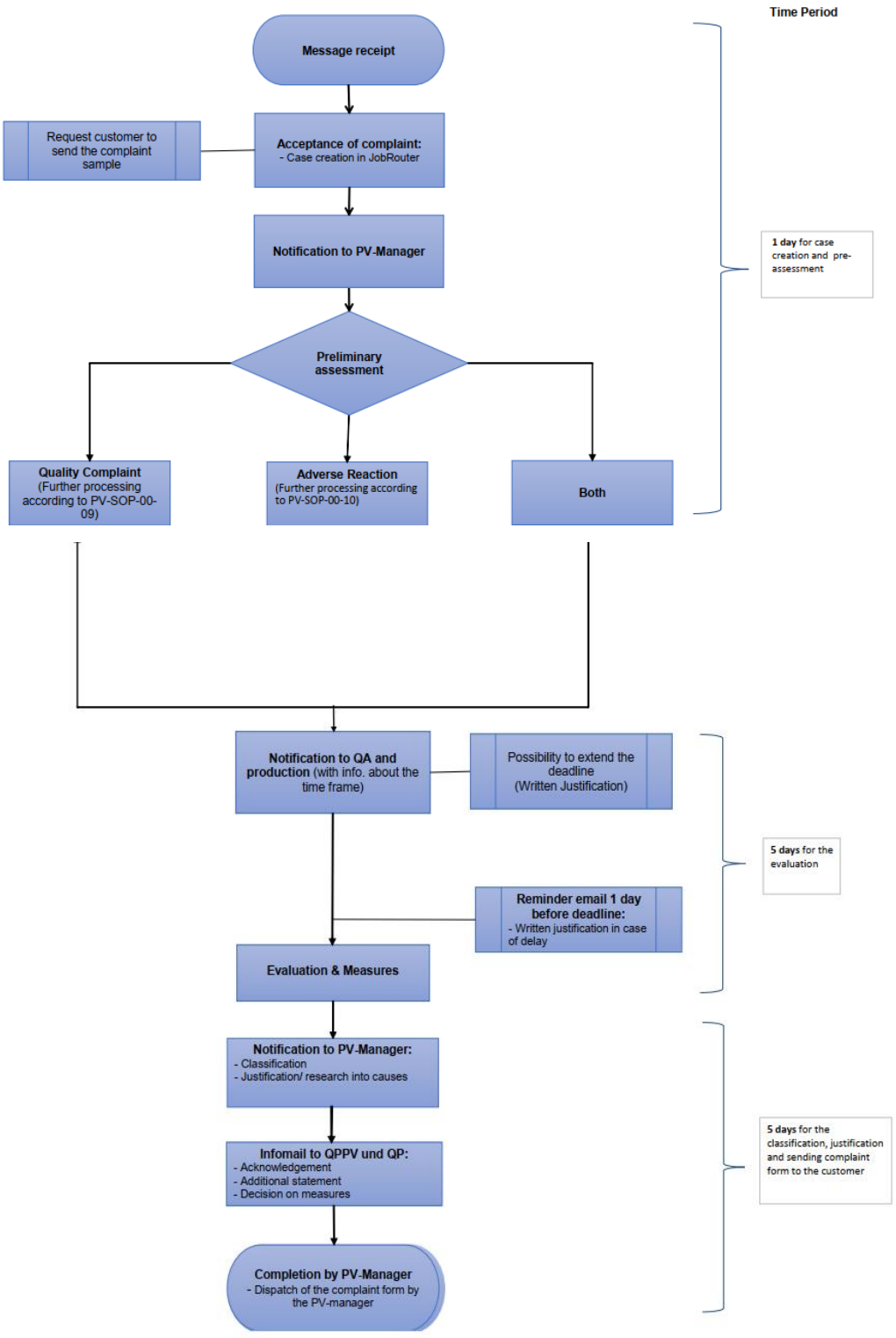

Figure 13: Flow Chart for JobRouter

6. Strategies to Improve the Complaint Handling System

After successful implementation of the complaint process in JobRouter, a meeting should be organised in the company where the process and timeliness will be explained to all the persons involved in the complaint handling. The following recommended complaint handling process should be explained to all the people involved in the complaint management system.

6.2. Recommended Complaint Handling Process in JobRouter

As shown in Figure 13, the complaint can be received by any person in the company. This person should be able to create a complaint case in the JobRouter, where he/she can give all the information related to the customer and complaint product. The person who receives the complaint can also request the customer to send a complaint sample or photograph. After giving all the information in JobRouter, an automatic notification will be sent to the PV manager responsible for complaint handling. This PV manager can do the pre-assessment of the complaint by deciding about the quality complaint, adverse reaction, or both. This step can be delegated from the QPPV to the PV manager to initiate the processing of the complaints faster, as the availability of QPPV is limited and it happened in the past that the pre-assessment was done late which also caused the delay of processing. According to the complaint handling SOP, the PV department should be informed within 24 hours after receiving complaints. Therefore, the pre-assessment should also be performed within 24 hours. The case creation of complaint in the JobRouter and pre-assessment of the complaint by the PV manager should take 1 day.

After a preliminary assessment, if the complaint is categorised as only a quality complaint or both adverse drug reaction and quality complaint, the processing can start according to the quality complaint SOP. At first, the automatic notification will be sent to the QA and production department for their evaluation with the information about the time frame of 5 working days. One day before the deadline, an automatic reminder will be sent to them to complete the evaluation. In case, if they cannot complete the evaluation within 5 days because of some reason, a written justification is required from them. The reason for the delayed response will also be sent to the customer. The evaluation from QA and production department can be performed by a specific investigator instead of the heads of departments to make the processing faster and to decrease the workload of the head of departments.

After the completion of the evaluation and investigation of the complaint, Job Router will send a notification again to the PV manager responsible for complaint handling. The PV Manager can classify the complaint as class 1, 2 or 3, according to the description mentioned in Table 1. After classification, the PV manager can summarise the reason by selecting the options mentioned in Appendix B in the complaint processing form. This step can also be replaced from the QPPV/QP to the PV-manager to make the processing of complaints faster.

At the end of each complaint, the acknowledgement must be made from the QPPV and the QP. According to the German Medicines and Active Pharmaceutical Ingredients Ordinance, the QPPV is responsible for collecting all known reports of drug risks, for recording all complaints, and for the coordination of necessary measures to prevent the drug risk, if exists (AMWHV § 19(1), 2021). Similarly, the necessary measures regarding the quality of the product must be brought to the attention of QP according to the German Medicines Act (AMG § 14, 2021).

After the classification, by the PV manager and acknowledgement by QPPV and QP, the complaint form can be sent to the customer by the company. The classification, justification of complaint by PV-manager and acknowledgement through QPPV and QP should also take 5 working days. In the end, the complaint process can be closed within 10 working days as per the complaint handling SOP.

Although the whole company must be trained in the complaint SOP, it is recommended to divide the participants into different groups according to their specific work and responsibilities. One training should be general for the employees who are not directly involved in complaint handling rather than receiving and transfer it to the responsible complaint manager. The other one should be specific with mentioned responsibilities and timelines for the employees involved in the complaint processing.

6.3. Sufficient Resources

There should be an increase in the number of skilled labours in the company to ensure that the complaints are managed effectively and timely following the regulations from regulatory authorities.

There is also a need to train the staff on how to manage the complaints effectively in the sector. According to chapter 8 EU-GMP Guide, sufficient trained personnel and resources

should be made available for the handling, assessment, investigation and review of complaints, and quality defects. Sufficient trained personnel and resources should also be available for the management of interactions with competent authorities.

6.4. Evaluation of the Strategies

To evaluate the strategies, some of the recommendations are already tested by the researcher to check the effectiveness of these strategies.

6.4.1. Follow-Up

One of the important reasons for delayed responses in the past years was lack of follow-up and a missing reminder to the departments involved in the processing and evaluation of complaints. The researcher tried to give a reminder to the departments regularly for each complaint received in 2021. Similarly, there was a regular follow-up with QA and production department for the complaints for which evaluations were still missing. The importance of timely response of complaints to the customer was also explained to the participants in interviews by the researcher. The following figure represents the processing time of complaints with follow-up from January to April in 2021.

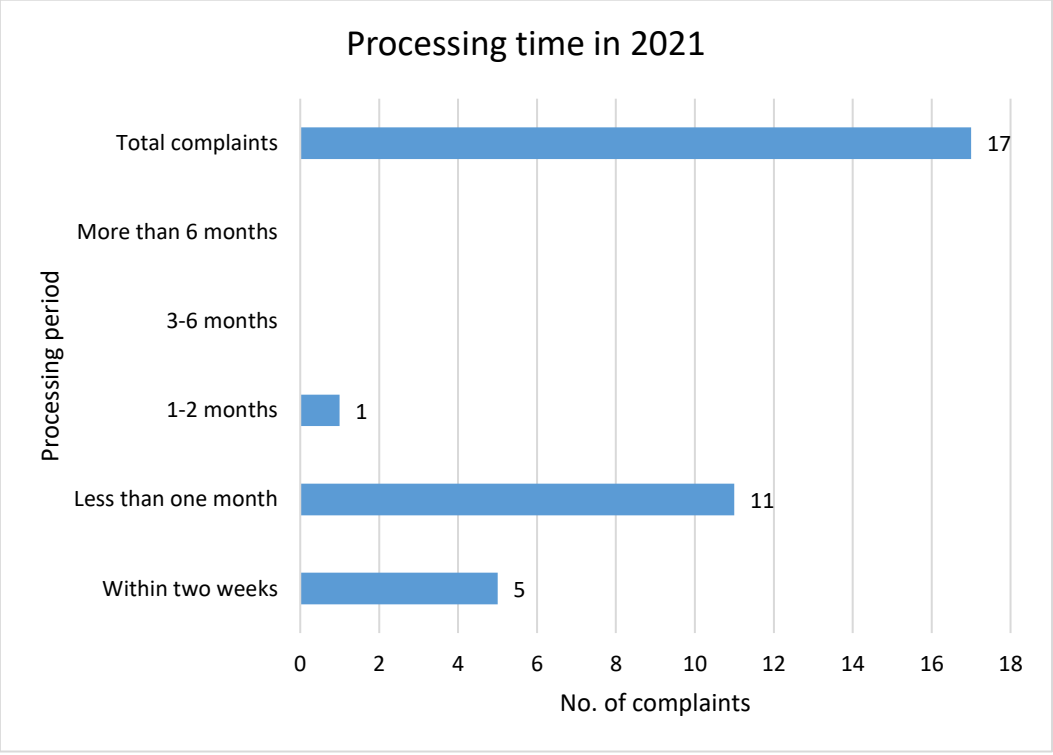

Figure 14: Processing time of complaints in 2021

The company received 22 complaints in total from January to April 2021. Out of these 22 complaints, 5 complaints were still open by the time of the end of this study because of some specific analytical investigations. Out of 17 closed complaints, 5 complaints were already processed in a proper time of two weeks. 11 complaints took less than one month to close and only one complaint took the processing time of more than one month. A huge difference can be seen in the processing time of complaints in 2021 by comparing the processing time in past years shown in Figure 8 (see page 30).

6.4.2. JobRouter for Handling Complaints

The researcher expects a great benefit from the digital system of JobRouter for handling complaints. This will help the company on one hand to process complaints faster and to provide automatic notifications and reminders to the persons involved in the complaint processing. On the other hand, all the information can be safely implemented and saved without losing data. As JobRouter can bring benefits to the company, it can also cause some disadvantages like a high cost for the company or long practical implementation time.

The researcher will plan an appointment with the company and JobRouter AG to discuss the process presented in the flow chart in Figure 13 and expects a positive response and a quick practical implementation of the complaint handling process in JobRouter.

7. Conclusion

This thesis has covered the complaint management system of a growing pharmaceutical company AqVida GmbH in Hamburg. Based on the qualitative research, it can be concluded that the company has been facing difficulties in handling complaints. As the company is growing rapidly, there is a need for an efficient system for complaint management. The analysis of the complaint documentation of the company from the year 2015 to 2020 showed that the number of complaints in 2020 increased nine times as compared to the number of complaints in 2015. The reason for the increase in the number of complaints is the production and marketing progress of the company. Until 2016 the company had been selling the products for the German market to other companies, which then marketed them under their respective brand names. This changed in 2017 when AqVida also entered the German market under its own name. Furthermore, the company started to manufacture the products at its manufacturing site in Dassow, Germany, in 2018. Today, the company is not only selling the products to other pharmaceutical companies but also directly supplying pharmacies and other institutions conducting clinical trials all over the world. In the reflection of this progress and the increased number of products, the burden on the maintenance of the complaint handling system was also high due to which the processing time of 10 working days according to the current SOP of the company was extended to several months.

The findings from the interviews also showed that the common reason for the extended time requirement was the lack of follow-up and the workload of the heads of departments involved in the processing and evaluation of complaints. Thus, the detailed assessment and relevant content of evaluation was lacking, which caused difficulties for PV managers in writing final response letters for the customers based on the assessment and evaluation of the root cause of complaints from the QA and production department. As a minor addition to that, the QPPV as the head of the department and as a final reviewer of the response letter, sometimes could not review the letter on the same day due to the high workload and limited availability.

The lack of specific complaint software for handling complaints causes irregularity in the complaint processing sequence. On the server of the company, the responsible persons found it challenging to follow up the sequence of the complaint's procedure. It was difficult to handle the complaint forms consisting of five pages to be filled in by five different people.

For example, since part of the evaluations had to be performed in parallel, a subsequent person did not necessarily know if the person who should make the prior assessment step was already finished. Due to these reasons, the processing sequence of complaints according to the current SOP was not followed.

To improve the complaint handling system, it is proposed in this thesis to name a specific person responsible for handling complaints and to connect different departments for the proper evaluation. Similarly, the heads of the department can assign the tasks to other colleagues in the department for detailed assessment and evaluation. The specific response letter for the customer can be replaced by a complaint form to make the handling faster and to give the customer an overview of all steps and evaluations performed by the company. This streamlined system of response is expected to have a positive impact on the customer by showing that the complaints are not forgotten but rather are taken seriously.

JobRouter can be a good tool to digitise and automate the complaint management system. It also provides a good overview of complaints to all the persons involved in the processing and evaluation to avoid any irregularity in the sequence and processing of complaints. The responsible PV manager for handling complaints can draw a statistical report from JobRouter every six months to check the repetitions of complaints with the same reason and to provide the status of complaints to the company. It can also be checked if specific measures are taken on the repeated complaints about the same reason. If for example five complaints of medicinal products come at different times but for the same reason, the PV manager can easily spot this and arrange a meeting with all responsible persons in the complaint management to discuss the specific measures to prevent these complaints in the future. The specific measures and actions taken at a proper time will improve patient care by minimising the drug risk.

Based on the findings of this study and the specific recommendations discussed in the previous chapters, the complaint management system in the company can be improved. The proposed measures were designed for an even higher number of complaints than is the case to date. This is important since continued growth of the company can be expected considering that approx. 70 % of the total amount of manufactured vials in 2020 were produced in 2021 until July already.

8. References

§ 19 **A**MG. (2021). Gesetz über den Verkehr mit Arzneimitteln (Arzneimittelgesetz – AMG) § 19 Verantwortungsbereiche. Retrieved 05.05.2021, from URL: https://www.gesetze-im-internet.de/amg_1976/__19.html

§ 19 **A**MWHV. (2021). Verordnung über die Anwendung der Guten Herstellungspraxis bei der Herstellung von Arzneimitteln und Wirkstoffen und über die Anwendung der Guten fachlichen Praxis bei der Herstellung von Produkten menschlicher Herkunft (Arzneimittel- und Wirkstoffherstellungsverordnung – AMWHV § 19 Beanstandungen und Rückruf). Retrieved 05.05.2021, from URL: https://www.gesetze-im-internet.de/amwhv/__19.html

Astalin, P. (2013). Qualitative Research Designs: A Conceptual Framework. International Journal Of Social Sciences & Interdisciplinary Research, 2, 119-122.

Bortz, J. & Döring, N. (2006). Forschungsmethoden und Evaluation für Human und Sozialwissenschaftler, 4. Überarbeitete Auflage. Springer Medizin Verlag. Heidelberg.

Bowen, G. A. (2009). Document Analysis as a Qualitative Research Method. In: Qualitative Research Journal, vol.9, no.2, pp.27-40. DOI 10.3316/QRJ0902027. Retrieved 22.04.2021, from URL: https://www.researchgate.net/publication/240807798_Document_Analysis_as_a_Qualitative_Research_Method

Braga, G.K. (2007). Complaint handling in pharmaceutical companies. The Quality Assurance Journal: The Quality Assurance Journal for Pharmaceutical, Health and Environmental Professionals, 11(1), 16-21. Retrieved 15.02.2021, from URL: https://doi.org/10.1002/qaj.398

Bundesministerium für Gesundheit. (2021). GMP – Die gute Praxis bei der Herstellung von Arzneimitteln. Retrieved 04.05.2021, from URL: https://www.bundesgesundheitsministerium.de/gmp.html

Cavana, R. Y., Delahaye, B. L., & Sekaran, U. (2001). Applied Business Research: Qualitative and Quantitative Methods (1st ed.). US & Australia: John Wiley & Sons Australia, Ltd.

Creswell, J. W. (2013). Qualitative inquiry and research design. Choosing among five approaches. 3rd Edition. SAGE publication.

Creswell, J. W. (2012). Educational research: Planning, conducting, and evaluating quantitative and qualitative research (4th ed.). Boston, MA: Pearson.

Creswell, J. W. (2007). Qualitative inquiry and research design. Choosing among five approaches. 2nd Edition. SAGE publication.

8. References

DiCicco-Bloom B. & Crabtree BF. (2006). The qualitative research interviews. Med Educ. 40:314-21.

Diekmann, A. (2006). Empirische Sozialforschung. Grundlagen, Methoden, Anwendungen. 16. Auflage. Rowohlts Enzyklopädie im Rowohlt Taschenbuch Verlag Reinbek bei Hamburg.

Dresing, T. & Pehl, T. (2015). Praxisbuch Interview, Transkription & Analyse. Anleitungen und Regelsysteme für qualitative Forschende. 6. Auflage. Marburg. Download at 22.05.2021, from Website: www.audiotranskription/praxisbuch

EMA. (2020). EudraVigilance. Retrieved 03.05.2021, from URL: https://www.ema.europa.eu/en/human-regulatory/research-development/pharmacovigilance/eudravigilance

EMA. (2016). Guidelines on good pharmacovigilance practices (GVP). Retrieved 05.08.2021, from URL: https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/guidelines-good-pharmacovigilance-practices-gvp-introductory-cover-note-last-updated-draft-revision_en.pdf

EMA. (2015). Pharmacovigilance. Retrieved 08.02.2021, from URL: https://www.ema.europa.eu/en/documents/leaflet/pharmacovigilance_en.pdf

European Union Guidelines to GMP. (2014). The rules governing medicinal products in the European Union. Volume 4. EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary use. Part 1. Chapter 8: Complaints, quality defects and product recall. Retrieved 04.05.2021, from URL: https://www.gmp-compliance.org/files/guidemgr/2014-08_gmp_chap8.pdf

Flick, U. (2016). Qualitative Sozialforschung. Eine Einführung. 7th ed. Reinbek: Rowohlt.

Frey, B. (2018). *The SAGE encyclopedia of educational research, measurement, and evaluation* (Vols. 1-4). Thousand Oaks, CA: SAGE Publications, Inc. doi: 10.4135/9781506326139

Fuß, S. & Karbach, U. (2014). Grundlagen der Transkription, Eine praktische Einführung, Barbara Budrich Verlag. Opladen und Toronto.

Hennik, M., Hutter, I., & Bailey, A. (2011). Qualitative Research Methods. London. SAGE publication Ltd. Retrieved 16.04.2021, from URL: https://books.google.de/books?hl=de&lr=&id=zN70kC0E3XQC&oi=fnd&pg=PP2&dq=qualitative+research+methods&ots=HXW8ZxpIzu&sig=9oC78RE4rlZ5dFjmDXuGJw9Tin8#v=onepage&q=qualitative%20research%20methods&f=false

Internal complaint investigation report Actavis. (2018). AqVida GmbH

Internal production statistics. (2019 & 2020). AqVida GmbH.

8. References

Internal SOP AqVida, PV-SOP-00-09 V3. (2021). Handling of complaints of finished products.

Internal SOP AqVida, PV-SOP-00-01 V1. (2021). Systemübersicht und Verantwortlichkeiten des Stufenplanbeauftragten.

Internal statistic AqVida. (2021). Marketing authorisations (MAs) of medicinal products from the registration database.

Investigation report Paclitaxel. (2015). Batch review.

Investigation report Oxaliplatin. (2015). Complaint form. Certificate of Analysis.

Investigation report Azathioprine. (2016). Complaint report AqVida.

Investigation Report Docetaxel. (2016). Report on the investigation of dislocation of rubber stopper toward vial. Complaint statement (18-2016).

Investigation report Paclitaxel. (2017). Complaint statement (05-2017).

Jamshed S. (2014). Qualitative research method-interviewing and observation. *Journal of basic and clinical pharmacy*, *5*(4), 87–88. https://doi.org/10.4103/0976-0105.141942

JobRouter AG. (2021). URL: https://www.jobrouter.com/en/

Kohlbacher, F. (2006). The Use of Qualitative Content Analysis in Case Study Research. Volume 7. Retrieved 19.04.2021, from URL: https://www.semanticscholar.org/paper/The-Use-of-Qualitative-Content-Analysis-in-Case-Kohlbacher/640535d580a4ab1e44bc6fa403c1c80eaf856fcb?p2df

Kuckartz, U. (1999). Computergestützte Analyse Qualitativer Daten. Eine Einführung in Methoden und Arbeitstechniken. Westdeutscher Verlag GmbH, Opladen/Wiesbaden.

Kumar, N., & Jha, A. (2015). A model of pharmaceutical customer complaints and redressal system. Volume-4. ISSN No 2277-8160. Retrieved 20.02.2021, from URL: https://www.researchgate.net/publication/308595149_A_Model_of_Pharmaceutical_Customer_Complaints_and_Redressal_System

Lavrakas, P. J. (2008). *Encyclopedia of survey research methods* (Vols. 1-0). Thousand Oaks, CA: Sage Publications, Inc. doi: 10.4135/9781412963947

Mayring, P. (2014). Qualitative content analysis: theoretical foundations, basic procedures, and software solution. Klagenfurt. Retrieved 17.02.2021, from URL: https://www.ssoar.info/ssoar/handle/document/39517

McElory, J. (2019). An introduction to adverse event reporting and product complaints for pharma companies. Retrieved 19.01.2021, from URL:

8. References

https://www.pharmaceuticalonline.com/doc/an-introduction-to-adverse-event-reporting-and-product-complaints-for-pharma-companies-0001

Ombudsman, Q. (2021). Complaints management. Queensland Ombudsman. Retrieved 03.05.2021, from URL: https://www.ombudsman.qld.gov.au/improve-public-administration/public-administration-resources/complaints-management

PIC/S. (2017). Standard Operating Procedure. Procedure for handling rapid alerts and recalls arising from quality defects. Retrieved 09.07.2021, from URL: https://www.gmp-compliance.org/files/guidemgr/PI_010_5_Rapid_Alert_SOP_1.pdf

Polit, F. D., & Beck, T. C. (2008). Nursing Research – Generating and Assessing Evidence for Nursing Practice.

Regulations (EU). (2016/161). Retrieved 30.07.2021, from URL: https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02016R0161-20210101&from=EN

Ritchie, J., Lewis, J., Nicholls, C. Mc. & Ormston, R. (2014). Design Issues. In: Qualitative Research Practice: A Guide for Social Science Students and Researchers. SAGE Publication. Los Angeles. Retrieved 16.04.2021, from URL: https://books.google.de/books?hl=de&lr=&id=EQSIAwAAQBAJ&oi=fnd&pg=PP1&dq=ethical+aspects+in+scientific+reserach+&ots=l_POmwSs0O&sig=1G8YoprMtbmwhRSJurJHWQbJCXI#v=onepage&q&f=false

Sanjari, M., Bahramnezhad, F., Fomani, F. K., Shoghi, M., & Cheraghi, M. A. (2014). Ethical challenges of researchers in qualitative studies: the necessity to develop a specific guideline. *Journal of medical ethics and history of medicine*, *7*, 14.

Segen, J.C. (2002). McGraw-Hill concise dictionary of modern medicine. The McGraw-Hill Companies, Inc., New York.

Tracy, S. J. (2013). Qualitative Research Methods. Collecting Evidence, Crafting Analysis, Communicating Impact, First Edition. Blackwell Publishing Ltd. Retrieved 16.04.2021, from URL: file:///Users/toqeerriaz/Downloads/Tracy,%20Qualitative%20Research%20Methods-%20Collecting%20Evidence,%20Crafting%20Analysis,%20Communicating%20Impact.pdf

Webster, S., Lewis, J. & Brown, A. (2014). Ethical Considerations in Qualitative Research. In: Qualitative Research Practice: A Guide for Social Science Students and Researchers. SAGE Publication. Los Angeles. Retrieved 20.04.2021, from URL: https://books.google.de/books?hl=de&lr=&id=EQSIAwAAQBAJ&oi=fnd&pg=PP1&dq=ethical+aspects+in+scientific+reserach+&ots=l_POmwSs0O&sig=1G8YoprMtbmwhRSJurJHWQbJCXI#v=onepage&q&f=false

8. References

World Health Organization (WHO). (2006). The safety of medicines in public health programmes: Pharmacovigilance an essential tool. Retrieved 08.02.2021, from URL: https://www.who.int/medicines/areas/quality_safety/safety_efficacy/Pharmacovigilance_B.pdf (08.02.2021)

World Health Organization (WHO). (2004). Guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. Geneva: World Health Organization. Retrieved 21.02.2021, from URL: https://apps.who.int/iris/bitstream/handle/10665/43034/9241592214_eng.pdf?sequence=1&isAllowed=y

9. Appendix

Appendix A: Complaint Acceptance Form

AQVIDA	**Reklamationsannahmeformular / Complaint receipt form**	PV-SOP-00-09.01
		Version 4
Seite 1 von 1	Reklamationsnummer:	Gültig ab: 19.11.2020

Annahme der Reklamation:

Name des annehmenden Mitarbeiters:		
Form der übermittelten Reklamation: ☐ schriftlich ☐ telefonisch	Datum:	Unterschrift:

Kundeninformationen:

Kunde / Apotheke / Firma:	
Adresse:	
Telefonnummer:	
Email-Adresse:	
Zusendung des reklamierten Fertigarzneimittels möglich:	☐ Ja ☐ Nein; Grund:

Informationen zum reklamierten Produkt:

Name des Produkts (ggf. Wirkstoff):	
Packungsgröße/Stärke:	
Chargennummer:	
Verfalldatum:	
Reklamationsursache:	
Ersatzlieferung gewünscht:	☐ Ja ☐ Nein

Vorabbewertung durch den Stufenplanbeauftragten:

Kategorisierung:	☐ Nebenwirkungsverdacht; Nr:		
	☐ Qualitätsreklamation		
Freigabe einer Ersatzlieferung vor Abschlussbewertung	☐ Ja	☐ Nein	☐ Nicht zutreffend
Datum:	Unterschrift:		

9. Appendix

Appendix B: Complaint Processing Form

AQVIDA	**Reklamationsbearbeitungsformular / Complaint evaluation form**	PV-SOP-00-09.04 Version 2
Seite 1 von 4	Reklamationsnummer:	Gültig ab: 19.11.2020

Informationen zum reklamierten Produkt:

Name des Produkts:	
Chargennummer:	
Reklamationsursache:	

Ersatzlieferung und Stellungnahmeversand durch Zulassungsmanager:

Ersatz für reklamiertes Produkt gesendet am:	
Anzahl der gelieferten Packungen:	
Stellungnahme an reklamierende Person versendet am:	
Datum:	Unterschrift:

AQVIDA	**Reklamationsbearbeitungsformular / Complaint evaluation form**	PV-SOP-00-09.04 Version 2
Seite 2 von 4	Reklamationsnummer:	Gültig ab: 19.11.2020

Evaluierung durch den Leiter der Qualitätskontrolle:

Datum:	Unterschrift:

9. Appendix

AQVIDA	Reklamationsbearbeitungsformular / Complaint evaluation form	PV-SOP-00-09.04
		Version 2
Seite 3 von 4	Reklamationsnummer:	Gültig ab: 19.11.2020

Evaluierung durch den Leiter der Herstellung:

Datum:	Unterschrift:

AQVIDA	Reklamationsbearbeitungsformular / Complaint evaluation form	PV-SOP-00-09.04
		Version 2
Seite 4 von 4	Reklamationsnummer:	Gültig ab: 19.11.2020

Bewertung durch die Sachkundige Person/Stufenplanbeauftragten:

Klassifizierung	☐ Klasse 1	☐ Klasse 2	☐ Klasse 3	☐ keine
Begründung bzw. Ursachenforschung	☐ Anwendungs-fehler	☐ Produktions-fehler	☐ Möglicher Transport-schaden	☐ Mängel am Ausgangs-material
	☐ Unsachgemäße Lagerung	☐ Nicht nach-vollziehbar	☐ Kein Mangel feststellbar, Beanstandung unbegründet	
	☐ Erstmaliges Auftreten	☐ Bekanntes Problem, Lösung wird erarbeitet	☐ Bekanntes Problem, Lösung ist erarbeitet	
Sonstiges, Bemerkungen: ☐ entfällt				
Maßnahmen falls erforderlich:	☐ Maßnahmen gemäß PV-SOP-00-04 (Alarm- und Maßnahmenplan)			
	☐ Info an Überwachungsbehörde	☐ Info an Hersteller		
	☐ Sonstiges:			
Datum:	Unterschrift:			

Appendix C: Project Information and Interview Guidelines

Project Information

Hello……,

My name is Hafsa Rasheed, a student of Master Health Sciences in the University of Applied Sciences in Hamburg.

I would like to invite you to participate in an interview for a research study on "Analysis, evaluation, and improvement of the complaint management system of a growing pharmaceutical company in Hamburg". The study aims to investigate the issues related to the complaint handling in the company to better understand the current problems and to propose the alternative solutions for the problems encountered by monitoring the complaint management system. The results gained from this study will help the company to improve the quality complaint handling system of their medicinal products.

If you agree to participate, you will be invited to a face-to-face/telephone interview. The interview will have open-ended semi-structured questions and will take around 30-45 min. The interview will be recorded with an electronic device for transcription if you agree to do so. Data will be recorded and stored in a secure and password protected computer.

Thank you very much!

Interview Guidelines

Interview guideline about complaint handling focusing on current problems in the processing and evaluation.

Introduction and Instructions

The purpose of this interview is to provide you with an opportunity to express your views, opinions, and perceptions about complaint management system in the company. Your input is extremely valuable and will help the company to improve the complaint handling process in the future.

The interview is divided into five parts.

Part I: Questions regarding your background information and experience in the complaint handling.

Part II: Questions refer specially to your main role in the complaint handling.

Part III: This part is about current situation and problems in the complaint handling and your satisfaction about the current system.

Part IV: This part is about training/ workshops if provided at the company.

Part V: In this part, there is an opportunity for you to provide your feedback and suggestions for the improvement of complaint management system in the company.

Many thanks in advance for your valued feedback!

9. Appendix

Type of Interview: Individual face-to-face/ telephone/ online interview
Interview date:
Interview duration:
Interviewer
Name: Hafsa Rasheed
Qualification: Student of Master Health Sciences (M.Sc.) (HAW)

Part I: Background Information of Interviewee

Name:
Functional area/department:
Position in the department:

1. How long have you had experience in handling complaints?
2. Do you have any experience with complaint handling from other companies? If yes, can you please explain the process there? Is the process same as here?

Part II: Role in the Complaint Handling

3. Can you explain me about your role in the complaint handling?
4. One specific question from analysis related to the person's tasks.
5. What circumstances lead to an extended time requirement for complaint handling?

Part III: Current Situation and Satisfaction from the Current System

6. What are the current problems in the processing and evaluation of the complaints in your point of view?
7. To what extent are you satisfied with the complaint management system of the company and why?

Part IV: Trainings/ Workshops

8. Did you get any training/ workshops for performing your job regarding complaint management/ handling at the company?

Part IV: Suggestions for Improvements

9. How can the complaint management system in the company be improved?
10. What are your expectations/ wishes regarding complaint management system?

Declaration of Authorship

I hereby declare that I have written and developed this thesis for the Master program in Health Sciences. The information provided for this thesis is duly acknowledged with proper citations and references. This master thesis has not been presented for another degree program or published anywhere else.

Hafsa Rasheed 16.08.2021, Hamburg