

LIFE SCIENCES

Quality and
Compliance

Complaint
management
Regulatory
requirements
Risk management

turning regulatory
requirements into
business benefit

why

wci

**“we can reduce
both the time
and cost
to handle
complaints”**

Product complaints are a fact of life. However, the pharmaceutical industry is unique; with its levels of regulation, complex nature of complaints, heightened consumer expectations, and the product and process improvement opportunities that complaints offer. Whilst a number of industries have more complex regulations, none have the range of possible complainants; whether sophisticated and knowledgeable prescribers, or patients with, in some cases, little understanding of the difference between an adverse event and a product complaint.

Given the need to meet diverse regulations and a variety of complainants, the industry has simply settled for handling complaints as expeditiously as possible, without really looking for long-term product improvements, customer service opportunities, or ongoing improvements to the complaints' handling process. Even the CAPA processes often drive a 'lip-service' attitude which fails to look deeply enough into complaints.

Typically, this has meant companies implementing a process that ticks the relevant local regulatory boxes and makes a basic attempt to correct ongoing issues; rarely revisiting the process to ensure it is effective and operating at optimum cost. The best case scenario is that the same complaint is prevented from reoccurring, but underlying product issues are rarely addressed. The best method for future communication with customers is not identified, and the prevention of similar issues in future products is not ensured.

So, how can companies make use of the complaint information and customer contact opportunities that a complaint provides?

In short, implementing a comprehensive complaints management system that covers:

1. **Definition:** Correctly identify complaints, separating technical complaints, adverse events, inquiries, efficacy issues and cosmetic concerns.
2. **Process:** Determine the appropriate route for closing complaints or required investigations.
3. **Product Improvement:** Incorporate lessons learned from the complaints into future changes to the product, and into current and future products with similar technology.
4. **Communication:** Ensure the correct feedback is provided to other teams in the company.
5. **Continuous Improvement:** Review the complaints' process to see how it may be further streamlined.

Definition: What is a complaint?

Getting the correct definition of what a complaint is and categorising it appropriately will ensure that regulations are met and it is suitably handled. Whilst the FDA definition offers some guidance¹, it leaves a number of areas open to interpretation.

It also leaves open such questions as whether a Medical Information Inquiry is due to poor information supplied with the

“we enable our clients to be more effective and efficient in protecting their patients and brand”

product, a legitimate product complaint, or a lack of understanding with the complainant. Linking such information is difficult unless a definition exists within the organisation to encompass such areas, so it would be better to have a definition that also adds 'labelling, packaging, shortages or other external complaints'. The definition should also include complaints raised internally.

This definition should then be communicated throughout the organisation.

The regulatory requirement of handling complaints becomes an opportunity to ensure complaints are captured correctly, and that safety and medical information inquiries are directed accordingly.

Process: Managing the complaints handling process

Once a complaint is received, whether from an external or internal source, it should initially be categorised to determine the best route for close-out. There are four categories defined:

1. Not a valid complaint.
2. Information for another team (e.g. Safety).
3. A valid complaint of a known type that can be handled with an *express* process.
4. A valid complaint that requires a deeper investigation.

“we offer a unique understanding of pharmacovigilance and the interactions with other business processes”

Category 1

Such complaints should not be disregarded, the fact that someone has complained provides an opportunity to enhance the perception of the company. Even if only a standard template is used, all complainants should receive a formal communication in their preferred method.

Category 2

Provide the information to the correct team, but communicate with the complainant to ensure they are aware of how the matter will be progressed. This not only enhances complainant perception, but may also prevent such incorrect reporting in the future.

Category 3

Companies should invest time to identify a number of expected complaints and prepare *template* investigation reports that can be quickly completed. Over time, the proportion of complaints addressed by this method should increase, thereby improving the effectiveness of the process.

Category 4

For this category it is necessary to determine the potential impact of the issue so that it can be correctly prioritised:

- a. Significant issue that could necessitate a product recall.
- b. Significant issue that could necessitate a batch recall.
- c. Issue that could cause future business loss either with this complainant or all users.
- d. New issue not seen before.
- e. Non-conformance (internally identified only).

“we enable global harmonisation and integration of regulated processes”

These categories combine both Medical and Technical complaints removing the need to have further sub-categories.

The regulatory requirement of handling complaints becomes an opportunity to ensure the right people address each complaint and the correct resolution is reached.

Product Improvement: Implementing future product improvements

All investigations will result in little more than resolution of immediate symptoms unless they are linked to a comprehensive method for the ongoing mitigation of issues. Many companies have implemented CAPA systems to address this issue, but few have linked these across multiple sites to prevent similar issues elsewhere, and fewer still are able to use this knowledge to prevent the same problems occurring in future developments.

For a CAPA system to really deliver value it must comprise the following:

1. Be available to all elements of the product manufacturing, distribution and marketing process, with proactive alerting of users when a relevant CAPA is created.
2. Be linked to the development team to ensure relevant issues are addressed for future products.
3. Contribute to improvements in the complaints handling process.
4. Link to a risk management system that addresses risks in the product.

“we can help to reduce risk in both current and future products”

CAPAs provide a real opportunity for substantial change and improvement, but are often relegated to token improvements that merely demonstrate a CAPA has been created. Linking CAPAs to ongoing product improvements can concentrate the correct resource on CAPAs and ensure they deliver real value.

Quality Circles – groups of knowledgeable people pulled from relevant areas of the business – provide ideal mechanisms for investigating and managing each CAPA. The questions they need to ask include:

- **Has the CAPA really addressed the issue on an ongoing basis?**
- **Can the CAPA be linked to other CAPAs to make a material change?**
- **Does the CAPA suggest additional changes?**
- **Is there a risk that future products will face the same issue?**

By doing this the expertise of people familiar with more detailed aspects of the supply chain is used to learn from CAPAs.

The regulatory requirement of handling complaints becomes an opportunity to improve future products.



Simplify what you do

to assure compliance and boost performance

Communication: Feedback

Not only should companies feed back to complainants, it is important they also ensure the correct information is provided to frontline teams, such as sales and marketing and supply chain, to ensure they are aware of the types of complaints and their resolution. Complaints may then be handled at source by informed people who will not only speedily address issues, but enhance the perception of the company.

The regulatory requirement of handling complaints becomes an opportunity to train the company.

**Continuous Improvement:
Improving the process**

The aim of the complaints' management process should not only be to reduce or eliminate customer complaints, but also to look to continuously improve the process.

Metrics should not only look at simple numbers, such as volume of complaints, but also at the time to resolve each category of complaint; how many new templates have been created; which future issues have been addressed; and what training has been provided.

The company should start with an assumption that all complaints take too long to address and look at ways to continually simplify the process through better template investigations or training.

The regulatory requirement of having a CAPA process becomes an opportunity to embed the right culture in the company and reduce risks to patient.

Conclusion

Implementing a comprehensive and integrated complaints' management

process will yield results across the company:

1. Reduced time and cost to handle complaints.
2. Improvements to current and future products.
3. Reduction of risks in current and future products.
4. Improved sales as a result of better training and enhanced customer perception.

Companies need to see complaints not just a regulatory burden, but as a valuable opportunity to make changes to their products and their perception in the market.



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