GMP/HACCP Audit and Upgrade Inspection Service Abstract

This document refers to the ensymm GMP/HACCP inspection procedure and Gap analyze for a GMP/HACCP upgrade for existing pharma/food plants

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What are GMP and HACCP?

Essential Production Standards

GMP is an abbreviation and stands for *Good Manufacturing Processes*. Simply spoken, it is a guideline to ensure certain quality standards. The WHO has defined the first GMP guideline in 1968 which has been refined over the years. WHO GMP rules can be seen as basic rules which have been optimized within the frame of development of European GMP or FDA (Food and Drug Administration/USA) rules. Further, the WHO guidelines get used as reference for local GMP rules or as major guidelines in case a country does not have its own GMP regulations.

HACCP or *Hazard analysis and critical control points*, is a systematic preventive approach to food safety and allergenic, chemical, and biological hazards in production processes that can cause the finished product to be unsafe, and designs measurements to reduce these risks to a safe level. In this manner, HACCP is referred as the prevention of hazards rather than finished product inspection. The HACCP system can be used at all stages of a food chain, from food production and preparation processes including packaging, distribution, etc.

Both standards reflect the guidelines which should be followed for pharmaceutical respectively food production. Many producers missed to set up their production lines according to these regulations for two reasons. Some investors come not originally from this business field. Therefore they are not aware about these standards and its importance. Some investors intend also to save money for the initial investment. But later many producers recognize, that competetors which follow these GMP/HACCP regulations have a better market position. Further many potential target markets require such a certification in order to protect its population.

Reasons for GMP and HACCP

Hence, it makes sense to upgrade your facilities for several reasons:

- You can produce more efficient
- You will extend your potential market due to regulative entry barriers
- You can increase your margins
- You protect yourself against low quality followers
- You will gain a better image
- You have a better marketing

The gap analysis tool gets provided by ensymm in order to compare the actual performance of Company X with the potential performance according to a higher GMP/HACCP production standard. At its core are two questions: "Where are we?" and "Where do we want to be?" Based on the given facts and the collected data by ensymm the current production can be considered as sub optimal.

As Company X does not make the best use of current resources, or foregoes investment in capital or technology, it produces or performs below its potential.
The gap analyzes in hand analysis and identifies gaps between the optimized allocation and integration of the inputs (resources), and the current allocation level. This reveals areas that can be improved. The Gap analysis involves determining, documenting, and approving the variance between the envisaged business requirements and current capabilities.

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How does our analysis look like?

In order to provide you a structured analysis we split the gap analysis in three main sections as those are identified to be mayor fields which need to be optimized. Ensymm identified the following three main sections:

- Production - in order to reach the envisaged capacity and quality the production requires modification in several areas
- Documentation - in order to reach a certificated high standard production, documentation needs to get developed/optimized
- Marketing - also the marketing approach should get adjusted to a sophisticated product

The third chapter will introduce the current product quality and the envisaged quality in order to be competitive in the market. In the following chapters ensymm will refer to the three main points to the left. Due to complexity and extent of each sector we subdivided the same in further chapters, coping with each single aspect separately.
The following content provides you a detailed overview of potential chapters for such a gap analysis. The final content will get adjusted to the individual project and client needs. Hence the analysis may refer to only one product or several products and by-products. Also the different envisaged standards may lead to an individual approach.

In order to illustrate the Gap between the current status and the standard you would like to reach, ensymm invented an individual approach for Gap analysis. Ensymm refers to the “single gaps” for each sensitive production section by illustrating the current status with a photo and an exemplarily photo how it should look like. This brings also non technicians into the position to evaluate the technical gap visually.

Main Points of the Gap Analysis

1. Project Background
2. Product
3. Production related Gaps
4. Documentation
5. Market
6. Summary and Road Map

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