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Summary

GMP for consultants

The purpose of Good Manufacturing Practice (GMP) is to ensure that the pharmaceutical products reaching the end users are safe and fulfil the intended purpose. GMP is set of practices for ensuring that products are consistently produced and controlled. It's obligated to follow GMP and everyone working under GMP must have enough knowledge of GMP, this also includes consultants.

There are several "GXP" requirements related to the development and management of drugs, e.g. Good Laboratory Practice (GLP) and Good Distribution Practice (GDP), these will not be mentioned here but focus is on GMP.

The GMP requirements are contained in the EU directive (91356 EEC, Eudralex Volume 4), and describe management, personnel, facilities and equipment, documentation, production, quality control, entrepreneurial activities, complaints and withdrawal, self-inspection.

GMP applies to everyone working whose work can influence the product and the pharmaceutical company must guarantee:

- The products are developed in accordance with GMP (other GXM could also apply)
- Production and control steps are clearly specified and easy to understand
- GMP is applied from raw materials and packaging materials via all intermediate steps to the finished product
- The finished product is manufactured and controlled in a correct manner in accordance with validated methods
- Each product, package and label is approved and controlled.
- Measures must be taken to ensure that products are stored, distributed and handled in such a way as to maintain quality during the shelf life of the product.

In broad terms, the process for the production and sale of medicinal products is as follows: When a drug has reached the final test phase (Phase 3), the company obtains manufacturing- and marketing authorization from the Swedish Medical Products Agency (SMPA, Läkemdelsverket). The authorization is based on proving that following pre-defined processes, the product will be safe for the end user and serve its purpose.

Note that this is an explanatory summary of GMP; consult the GMP standards for complete reference.

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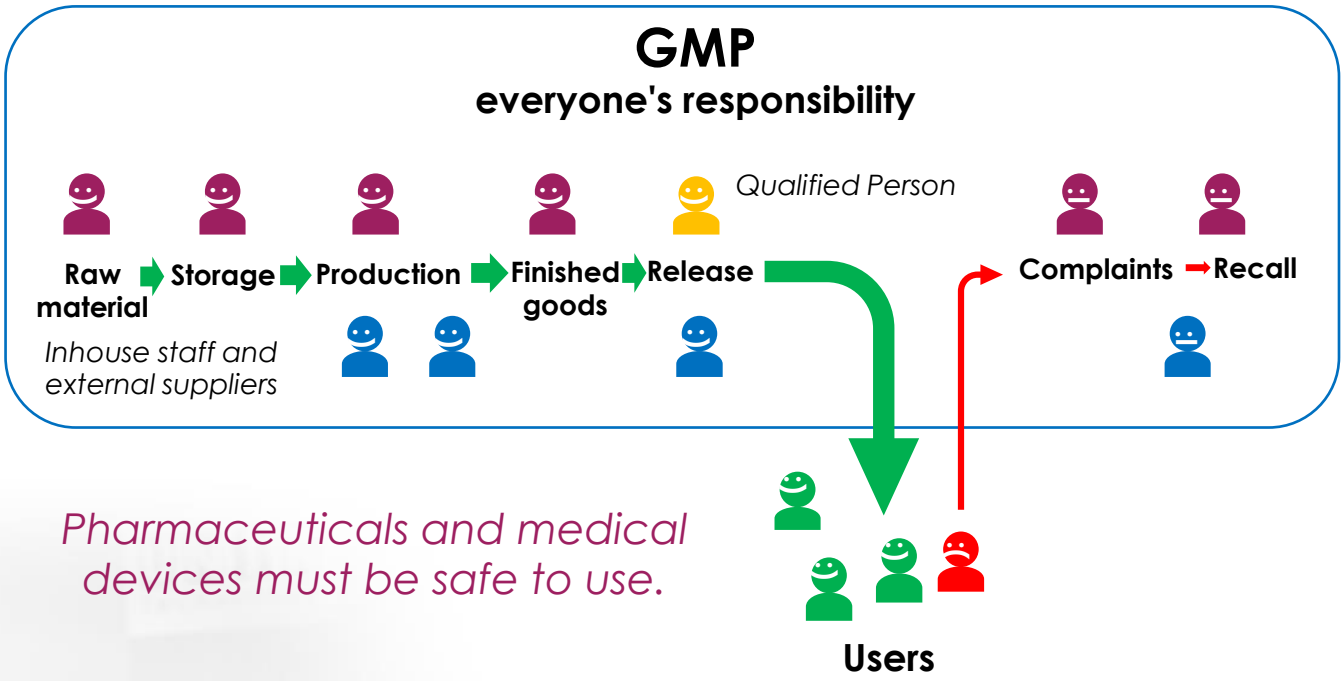
The practices are written down in steering documents that the company must issue and follow, the outcome when these are followed is reflected in the accounting documents. If the outcomes are within approved tolerances, a Qualified Person from the company can approve the product for release on the market. A product may serve one or more purposes for these purposes: (1) Detecting disease, (2) Preventing disease or (3) curing disease.

Once on the market, all defects reported by end-users must be investigated and depending on the outcome, the pharmaceutical company must always be able to instantly stop the use of the product and withdraw it from the market.

The pharmaceutical company must have an independent quality department, approved by the SMPA, who conduct self-inspections to ensure compliance with GMP.



Key takeaway for consultants who wants to take assignments within companies who follow GMP guidelines – you must prove to have sufficient knowledge within GMP for your intendent role.

Note that this is an explanatory summary of GMP; consult the GMP standards for complete reference.

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