

Free Guide

GMP: Good Manufacturing Practice – Quality Assurance



Skills management software
for frontline workers

www.ag5.com | info@ag5.com | +31 20 463 0942

What is a GMP certification?

GMP, or Good Manufacturing Practices, is a set of international quality assurance standards and guidelines applied across various industries to ensure the consistent production of safe, high-quality products, including pharmaceuticals, food, and cosmetics.

Who needs a GMP certification?

GMP certification is typically mandatory for companies and organizations involved in the manufacturing and production of products in industries where product quality, safety, and consistency are critical. The industries and businesses that often need GMP certification include those involved in:

- Pharmaceutical manufacturing
- Food manufacturing
- Cosmetic manufacturing
- Biotechnology
- Medical device manufacturing
- Chemical and chemical product manufacturing
- Animal health and veterinary product manufacturing

The benefits of implementing GMP certification

Implementing GMP offers several benefits to organizations. Some key advantages include:



Quality assurance

GMP helps ensure consistent product quality by establishing rigorous standards and procedures for manufacturing, testing, and documentation.



Compliance and regulatory approval

Adhering to GMP guidelines is often a regulatory requirement in many industries. Compliance with GMP standards can expedite regulatory approvals and reduce the likelihood of non-compliance issues or product recalls.



Cost reduction and efficiency

GMP promotes efficient and standardized manufacturing processes, reducing waste, rework, and operational costs.

How to get a GMP certification

Earning a GMP certification involves understanding industry-specific regulations, preparing detailed documentation, implementing GMP standards, providing employee training, conducting regular audits, and undergoing third-party assessments. Compliance, corrective actions, and continuous improvement are also key elements in obtaining and maintaining the certification, ensuring product quality and safety.

How long does it take to get a GMP certification?

It typically takes between three and 12 months to earn a GMP certification, depending on an organization's current processes and how many must be changed or otherwise altered to adhere to GMP standards.

Challenges in implementing GMP

Implementing GMP standards may pose several challenges to organizations. They include:



Cost and resource allocation

Meeting GMP standards often requires significant financial investments in facility upgrades, equipment, and personnel training. Allocating these resources can be challenging for smaller companies or those with limited budgets.



Complex regulatory compliance

GMP regulations can be intricate and vary by industry and region. Staying up-to-date and ensuring full compliance can be daunting, especially when multiple regulations apply to a single organization.



Cultural and behavioral shifts

Implementing GMP requires a cultural shift toward quality and compliance throughout an organization. Changing employee behaviors and attitudes to prioritize GMP principles can be challenging and may face resistance.

Tips and strategies for preparing for GMP certification

Here are a few tips for earning a GMP certification:

- Ensure that all employees are well-informed about GMP principles and practices through comprehensive training programs.
- Maintain meticulous records of all processes, procedures, and quality control measures.
- Conduct regular internal audits and self-inspections to proactively identify and address compliance gaps.
- Invest in the upkeep and (preventive) maintenance of manufacturing facilities and equipment to ensure they meet GMP standards.
- Collaborate with GMP experts and consultants to assess your processes and facilities, receive guidance on compliance, and prepare for third-party audits.

Renewal requirements for GMP certification

A GMP certification is typically valid for three years. Renewal involves regular audits by certification bodies, updated documentation to demonstrate continued compliance, ongoing employee training, and adherence to evolving GMP standards and regulations.

Resources for GMP certification

For more information and guidance on GMP compliance, you can refer to the following resources

Regulatory bodies. The [European Medicines Agency](#), [International Society for Pharmaceutical Engineering](#), [US Food & Drug Administration](#), and other regulatory bodies provide a wealth of information regarding GMP and GMP certification.

Accredited certification bodies. [GMP Plus International](#) provides a global database of accredited certification bodies for GMP, which you can use to find and contact an organization that can help you take steps toward earning a GMP certification.

GMP skills matrix. AG5 offers a [free skills matrix](#) dedicated to GMP-related skills. You can use it to identify, track, and manage the skills your employees possess, as well as those they may need, for your organization's GMP certification.

cGMP vs. GMP

Current Good Manufacturing Practices (cGMP) is a term used mainly in the United States, while GMP is a more generic and widely used term that can apply globally. Both cGMP and GMP are essential for regulating and maintaining the quality and safety of products in their respective industries, but the specific regulations and requirements may differ based on jurisdiction and industry.

Additionally, cGMP places increased focus on using the latest and most innovative technologies to ensure quality standards, hence "current." Companies operating in regulated industries need to be aware of and comply with the relevant cGMP or GMP standards applicable to their specific products and geographic regions.

Skills management

Skills management for GMP and cGMP

AG5 stores all certifications in the cloud, providing all authorized personnel with access to the right version of approved certifications. This helps you easily keep track of all data and documentation related to GMP compliance across your organization.

Using AG5's skills management software, you can monitor the status of any type of certification that is relevant to your workforce, leveraging intuitive dashboards that provide you with a clear understanding of exactly what is needed to keep your employees skilled and safe.

[Book a demo](#)

FAQs about GMP

What is the scope of GMP?

The scope of GMP is to ensure the quality and safety of pharmaceuticals, food, and other regulated products by establishing manufacturing standards.

Is a GMP certification mandatory?

A GMP certification is typically mandatory for industries such as pharmaceuticals and food to ensure product safety and quality.

How long does it take to earn a GMP certification?

The time to earn a GMP certification varies depending on the specific program and organization, but typically takes three to 12 months to complete.

What are the cost considerations for GMP certification?

Cost considerations for GMP certification include training, documentation, audits, and potential facility upgrades, which can vary significantly based on the industry and organization size.

What is the validity period for a GMP certification?

A GMP certification is typically valid for three years.

Can GMP be integrated with other management systems?

Yes, GMP can be integrated with other management systems such as [ISO 9001 \(Quality Management\)](#) and [ISO 14001 \(Environmental Management\)](#) to streamline processes and enhance overall quality and compliance.

How can you learn more about GMP certification?

Visit the websites of the [European Medicines Agency](#), [International Society for Pharmaceutical Engineering](#), [US Food & Drug Administration](#), or other regulatory bodies.

Sources

Good manufacturing practice. European Medicines Agency.

<https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice>

Good Manufacturing Practice (GMP) Resources. International Society for Pharmaceutical Engineering. <https://ispe.org/initiatives/regulatory-resources/gmp>

GMP-inspecties en GMP-certificaat. Inspectie Gezondheidszorg en Jeugd. <https://www.igj.nl/zorgsectoren/geneesmiddelen/productie-gmp/gmp-inspecties-en-certificaat>

Facts About the Current Good Manufacturing Practices (CGMP). US Food & Drug Administration. <https://www.fda.gov/drugs/pharmaceutical-quality-resources/facts-about-current-good-manufacturing-practices-cgmp>

Find Certification Bodies. GMP Plus International.

<https://www.gmpplus.org/en/certification/find-certification-bodies/>

Author



[Rick van Echtelt](#)

Rick van Echtelt is the Co-Founder and CEO of AG5, where he leverages over two decades of experience in entrepreneurship and developing skills management software.

[Read author profile](#)

Revisions

Original version | September 7, 2023

Written by: [Rick van Echtelt](#)

[Please read our editorial process for more information](#)



Skills management software
for frontline workers