Key Milestones That Shaped the History of GMP

A 40-slide guide from early drug safety failures to modern quality systems.

LEARNING GOAL

Why this history matters

GMP history is not only a list of dates. It explains why today's controls exist in pharmaceutical manufacturing.

- Connect patient harm with quality controls
- Understand inspection expectations faster
- Explain GMP evolution in interviews

What changed:

Historical failures became modern safeguards for patients.

CORE IDEA

GMP in one sentence

Good Manufacturing Practice is a system that ensures medicines are consistently produced and controlled according to quality standards.

- Quality must be built into the process
- Records must prove what really happened
- People, equipment, materials, and systems must stay controlled

What changed:

GMP turns quality from a final check into daily discipline.

BEFORE REGULATION

Final testing was not enough

Early manufacturers often relied on finished-product testing. However, testing could miss contamination, mix-ups, weak procedures, and hidden process failures.

- Testing is limited by sampling
- Process failures can remain invisible
- Quality needs prevention, not only detection

What changed: **Modern GMP moved quality upstream into the process.**

PART 1

Patient harm created the need for GMP

The first milestones show why drug safety laws and manufacturing control became unavoidable.

1906

Pure Food and Drugs Act

The United States began stronger federal control over adulterated and misbranded medicines and foods.

- Targeted false labeling and adulteration
- Improved basic consumer protection
- Started a stronger regulatory foundation

Drug quality became a public health responsibility.

1937

Elixir Sulfanilamide disaster

A toxic solvent used in a medicine caused many deaths and exposed major gaps in pre-market safety control.

- No adequate safety testing before sale
- Weak formulation oversight
- Public pressure for stronger law

Safety evidence became essential before medicines reached patients.

1938

Federal Food, Drug, and Cosmetic Act

The FD&C Act gave FDA stronger authority over drug safety, factory inspections, and product standards.

- Required stronger safety evidence
- Expanded inspection authority
- Strengthened rules against unsafe products

Regulators gained more power to prevent unsafe medicines.

1941

Sulfathiazole contamination case

Contaminated sulfathiazole tablets showed that batch-level controls were necessary, not optional.

- Contamination caused serious patient harm
- Batch controls became more important
- Procedures and segregation needed discipline

Manufacturing control became as important as product testing.

1940s

Mass production pressures

Large-scale medicine production increased complexity and made uncontrolled variation more dangerous.

- More batches meant more risk
- Operators needed standard procedures
- Records became critical evidence

Scale required repeatable systems, not informal habits.

1950s

Quality control expands

Pharmaceutical firms increasingly used formal QC laboratories and batch documentation to manage growing product volume.

- More laboratory testing
- More formal records
- Greater attention to production control

Quality control became more organized and visible.

1961

Thalidomide crisis

The thalidomide tragedy reinforced the need for stronger safety, evidence, and regulatory review before drug approval.

- Global patient harm shocked regulators
- Drug development evidence gained importance
- Risk evaluation became more urgent

Drug safety became a stronger global regulatory priority.

1962

Kefauver–Harris Amendments

These amendments strengthened U.S. drug law by requiring stronger proof of safety and effectiveness.

- Required substantial evidence of efficacy
- Improved informed consent expectations
- Strengthened manufacturing oversight

Approval and manufacturing expectations became stricter.

1963

First FDA drug GMP regulations

FDA published formal GMP requirements for drug manufacturing, processing, packing, and holding.

- Minimum manufacturing standards
- Written procedures and records
- Facility and equipment expectations

GMP became a formal regulatory framework for drug production.

1968

WHO adopts GMP draft text

WHO adopted its first GMP text, giving countries an international reference for medicine quality.

- Supported global public health
- Created shared quality language
- Helped regulators compare expectations

GMP started becoming an international standard.

1969

WHO Certification Scheme

WHO integrated GMP into its Certification Scheme for pharmaceutical products moving in international commerce.

- Supported cross-border medicine quality
- Linked GMP with product certification
- Helped strengthen regulatory trust

GMP became connected to global medicine trade.

1970

PIC is founded

The Pharmaceutical Inspection Convention began supporting mutual recognition and harmonization of inspections.

- Focused on GMP inspections
- Promoted inspector cooperation
- Reduced duplicated inspection burden

Inspection harmonization became a regulatory goal.

1978

21 CFR Parts 210 and 211

FDA finalized modern cGMP regulations for human and veterinary drug products.

- Defined manufacturing controls
- Strengthened quality unit responsibilities
- Codified documentation and production expectations

cGMP became the operational backbone of U.S. drug manufacturing.

GMP becomes a quality system

From the late 1970s onward, GMP moved beyond final testing into prevention, validation, risk management, and lifecycle control.

Why “current” matters

The word “current” reminds manufacturers to use up-to-date science, technology, and quality expectations.

- Old systems may no longer be acceptable
- Controls must match today’s risks
- Continuous improvement is part of compliance

What changed:

cGMP is not frozen in history. It must stay current.

1980s

Validation culture grows

Pharma quality expectations increasingly focused on proving that processes, equipment, and systems perform reliably.

- Process validation became central
- Equipment qualification expanded
- Cleaning validation gained importance

Manufacturers had to prove control before relying on routine output.

1989

EU GMP Guide development

European GMP guidance developed into a detailed reference for medicinal-product manufacturing across Europe.

- Common GMP interpretation
- Stronger documentation expectations
- Foundation for EudraLex Volume 4

EU GMP became a key global reference for manufacturing quality.

1990

ICH is established

ICH created a platform for harmonizing technical requirements across major regulatory regions.

- Reduced duplicated technical expectations
- Supported global development
- Improved shared quality language

Harmonization became central to global pharmaceutical quality.

1995

PIC/S is founded

PIC/S expanded cooperation among inspectorates and supported international GMP inspection consistency.

- Inspector training and cooperation
- Harmonized GMP standards
- Stronger inspection system quality

Inspection systems became more globally connected.

1997

Electronic records and signatures

Electronic data and computerized systems made data integrity a core GMP concern.

- Electronic records needed controls
- Audit trails became important
- Access and security required discipline

Digital systems had to become trustworthy GMP evidence.

2000

ICH Q7 for APIs

ICH Q7 introduced harmonized GMP guidance for active pharmaceutical ingredients.

- API quality systems
- Documentation and traceability
- Quality unit independence

API manufacturing gained a stronger global GMP framework.

2003

EU GMP legal principles updated

European GMP expectations for medicinal products were strengthened through updated legal principles and detailed guidance.

- Human medicines GMP principles
- Manufacturer and importer responsibilities
- Stronger regulatory interpretation

GMP responsibilities became clearer across the EU.

2005

ICH Q8: Pharmaceutical Development

ICH Q8 promoted deeper product and process understanding during pharmaceutical development.

- Quality by Design thinking
- Critical quality attributes
- Control strategy development

Quality moved earlier into product and process design.

2005

ICH Q9: Quality Risk Management

ICH Q9 gave pharma teams a structured approach to identifying, evaluating, and controlling quality risks.

- Risk-based decisions
- Scientific prioritization
- Better deviation and change evaluation

GMP decisions became more systematic and risk based.

2008

ICH Q10: Pharmaceutical Quality System

ICH Q10 described a comprehensive quality system model across the product lifecycle.

- Management responsibility
- CAPA and change management
- Continual improvement

GMP became part of a lifecycle pharmaceutical quality system.

PART 3

Modern GMP is lifecycle control

Today’s GMP expectations connect people, processes, data, suppliers, facilities, and product lifecycle knowledge.

2011

EU documentation updates

EU GMP documentation expectations reinforced clear records, controlled instructions, and reliable evidence.

- Good documentation practice
- Batch record discipline
- Traceability of decisions

Documentation became a daily proof of GMP control.

2013

EU Chapter 1 and PQS thinking

EU GMP Chapter 1 aligned more closely with pharmaceutical quality system concepts.

- Quality risk management
- Product quality review
- Senior management responsibility

Quality systems became a leadership and lifecycle responsibility.

2015

Lifecycle process validation

Validation expectations increasingly focused on process lifecycle, knowledge, and continuous verification.

- Qualification and validation planning
- Continued process verification
- Change control discipline

Validation became ongoing evidence, not a one-time event.

2018

Data integrity becomes central

Regulators increasingly emphasized that data must be complete, consistent, accurate, and attributable.

- ALCOA+ principles
- Audit trail review
- Computerized system governance

Reliable data became essential to prove product quality.

2022

EU GMP Annex 1 revision

Sterile manufacturing expectations strengthened contamination control, risk management, and cleanroom discipline.

- Contamination Control Strategy
- Barrier technology focus
- Aseptic behavior and monitoring

Sterile GMP shifted toward proactive contamination prevention.

2023

ICH Q9(R1) modernization

The revised Q9 strengthened quality risk management by addressing subjectivity and formality.

- Better risk communication
- Appropriate formality
- Less bias in risk decisions

Risk management became more mature and practical.

PRACTICAL LESSON

From final testing to quality systems

The biggest lesson in GMP history is simple: quality cannot be tested into a medicine after weak manufacturing.

- Design the process correctly
- Control materials, equipment, and people
- Use data to improve the system

What changed:

Modern GMP prevents problems before they reach patients.

Interview questions from GMP history

- What event led to stronger drug safety laws?
- Why was cGMP introduced?
- How did WHO and ICH globalize GMP?
- Why is final testing not enough?
- How does GMP history affect daily QA work?

Use every answer to connect history with patient safety and process control.

Sources and next step

- FDA history of drug regulation and cGMP final rule
- WHO GMP standards and Certification Scheme history
- European Commission EudraLex Volume 4
- ICH Q7, Q8, Q9, and Q10 quality guidelines
- PIC/S history and GMP harmonization resources

Download, share, and use this deck as a practical GMP timeline guide.