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Historical developments of Good Manufacturing Practices

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The pharmaceutical industry is the most regulated of all industries. Think of any drug on the market today to treat a disease, a chronic condition, or even something as mundane--and confounding--as the common cold. No drug would be available without the teams of medical researchers and other specialists who worked to make sure it received regulatory approvals.

Definition: Good Manufacturing Practice or GMP (also referred to as 'cGMP' or 'current Good Manufacturing Practice') is a term that is recognized worldwide for the control and management of manufacturing and quality control testing of foods, pharmaceutical products, and medical devices

GMP is part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards (ex: identity, strength, quality, and purity) appropriate to their intended use and as required by the Marketing Authorization or product specification"

Why GMP were Implemented: Good Manufacturing Practices were put in place in response to disasters in the pharmaceutical industry. Most requirements were put in place as response to tragic circumstances and to prevent future tragedies. Everyone in our industry should know the story of how the good manufacturing practices (GMPs) have come to be.

What are those Disasters?

- 1906- Cocaine found in cola (Published in Daily Plant Newspaper)
- 1938- Hundreds Die from Sulphanilamide Misformulation
- 1941- Nearly 300 deaths and injuries result from sulfathiazole tablets contaminated with the sedative; phenobarbital.
- 1962- Thousands of Babies deformed in Thalidomide Disaster
- 1974- Thirteen die using IUD contraception
- 1990- Aids caused by contaminated blood products
- 1994- Pace makers can lead to sudden death

What is GMP?

- Good manufacturing practice (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.
- GMP covers all aspects of production; from the starting materials, premises and equipment to the training and personal hygiene of staff. Detailed, written procedures are essential for each process that could affect the quality of the finished product. There must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process - every time a product is made.

To obtain and maintain GMP compliance, every manager and supervisor should provide frequent, meaningful GMP reminders, train and develop all employees, and fully participate in formal, ongoing training programs. Senior management must state publicly and make it clear through their actions that following GMPs is the only way their company does business.

If you want people to move toward regularly following GMPs, they have to know why: why the regulations came about and what's in it for all of us as consumers to see them followed. Most requirements were put in place as responses to tragic circumstances and to prevent future tragedies.

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