How and Why The United States Protects Food and Drug Products

The Food and Drug Administration (FDA)
Good Manufacturing Practice (GMP)
Quality Management Systems (QMS)

Module 1, Lesson 3

How were items produced before the Industrial Revolution?

Production of goods and services before the 18th century

- Goods were made in small quantities, by hand. There were no factories.
- Most people were not literate, so production methods were passed down orally.
- There were no 'universal' standards for quality.
- The fields of Chemistry and Biology were not yet well developed.

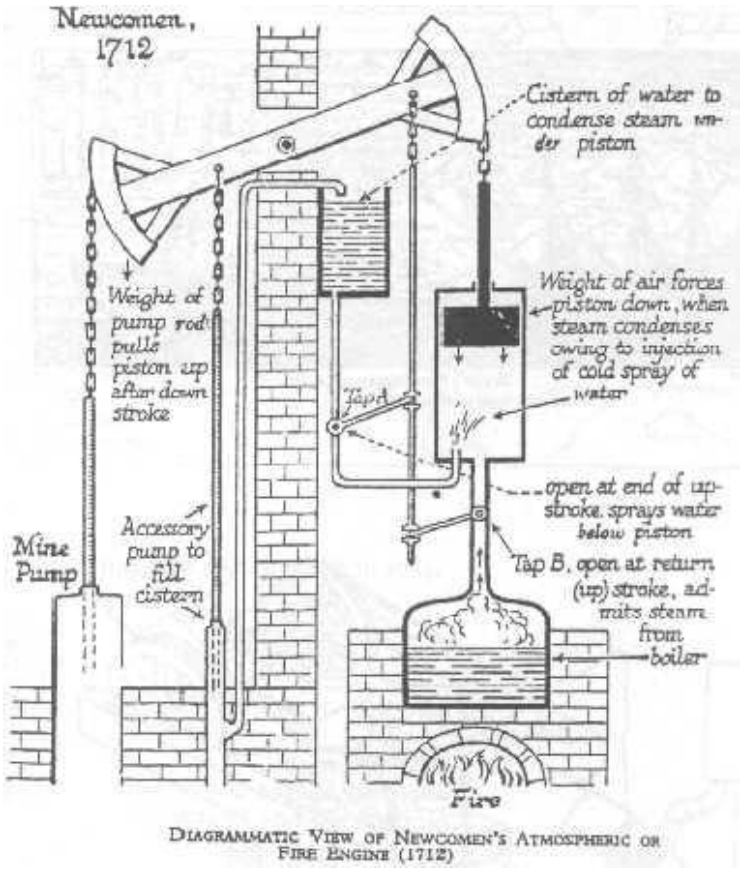


Medievalists.net



Industrial Revolution (1799-1900´s):

- Fueled by the harnessing of steam power, the Industrial Revolution began in Great Britain
- Steam engine: Using steam power to perform work and to transport goods
- The creation of machines to produce products and to transport products led to the expansion/creation of many industries:
  - Textile Industry
  - Chemical industry
  - Mining industry
  - Military industry

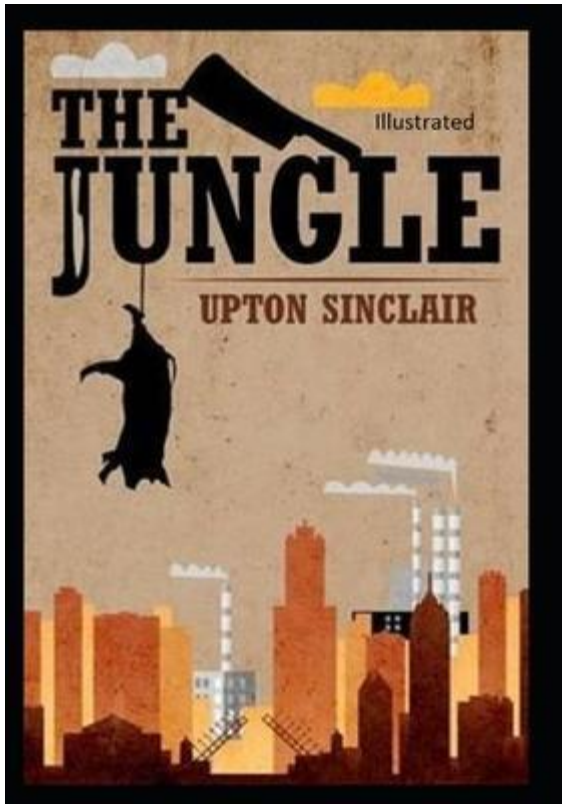


DIAGRAMMATIC VIEW OF NEWCOMEN'S ATMOSPHERIC OR FIRE ENGINE (1712)

https://quizlet.com



Unexpected literary origin of production standards



Watermarkbooks.com

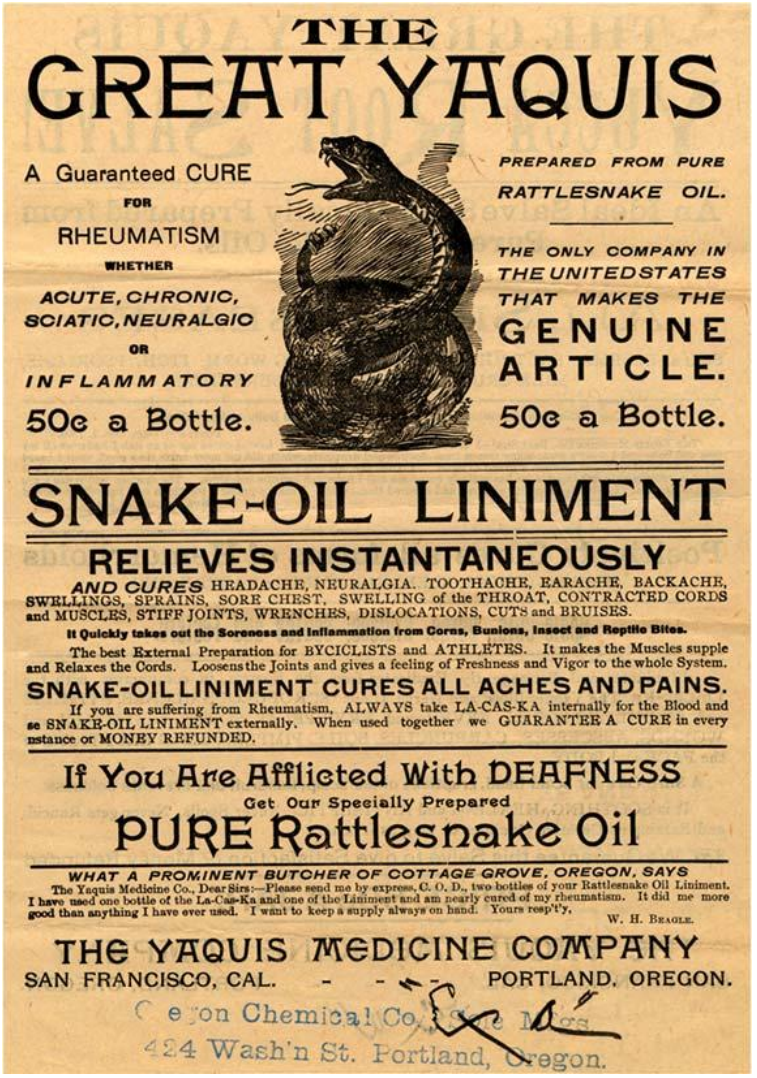
- 1906: “The Jungle” (Upton Sinclair) is published.
- It described the current (1906) practices in the Chicago meat-packing industry:

  "This is no fairy story and no joke; the meat will be shoveled into carts and the man who did the shoveling will not trouble to lift out a rat even when he saw one.” (Chapter 14)

- These descriptions had a high impact on public opinion.
- The book generated an early awareness of safety and the need for legal standards in the food processing industry.

Books Like ‘The Jungle’ and Articles by Journalists Exposed Unsafe Practices in the Production of Medicines

- Fraudulent claims
- Harmful ingredients like alcohol



Dafont.com

1906 Congress Passes:
Pure Food and Drug Act
Federal Meat Inspection Act

Pure Food and Drug Act

- The main purpose was to ban foreign and interstate traffic in adulterated or mislabeled food and drug products
- It directed the U.S. Bureau of Chemistry to inspect products and refer offenders to prosecutors.
- It required that active ingredients be placed on the label of a drug's packaging and that drugs could not fall below purity levels established by the United States Pharmacopeia or the National Formulary.
- Led to the creation of the FDA



The Pure Food and Drug Act Did Not Regulate Cosmetic Products or Medical Devices



In 1933, women were blinded and one died from infections after using the eye lash dye, Lash Lure, which contained a harmful chemical dye.

1938 Congress Passes: Food, Drug and Cosmetic Act

- Gives the FDA authority to regulate: Food, Drugs, Cosmetics, Medical Devices
- Manufacturer must prove safety and efficacy BEFORE marketing
- Drugs had to be approved by FDA before marketing
- Truthful labeling and advertising reviewed by FDA

1941: Another Tragedy Led to the Creation of Good Manufacturing Practices (GMP)



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- Sulfathiazole, an antibiotic, contaminated with phenobarbital (a sedative) injured multiple patients.
- In response, the FDA revised manufacturing and quality control requirements.

Good Manufacturing Practices (GMP)

The practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of:

- Food
- Beverages
- Cosmetics
- Pharmaceutical Products
- Dietary Supplements
- Medical Devices













GMPs are enforced in the United States by the U.S. Food and Drug Administration (FDA), under Title 21 CFR.

Good Manufacturing Practices (GMP)

These guidelines provide minimum requirements that a manufacturer must meet to assure that their products are consistently high in quality, from batch to batch, for their intended use.

The main purpose of GMP is always to prevent harm from occurring to the end user.

Additional tenets include:

- Ensuring the end product is free from contamination
- Ensuring the end product is consistent in its manufacture
- Ensuring that its manufacture has been well documented,
- Ensuring that personnel are well trained
- Ensuring that the product has been checked for quality more than just at the end phase.

GMP is typically ensured through the effective use of a quality management system (QMS)

The Three Pillars of GMP



- Safety

  The medicine will be safe to use.

- Quality

  The medicine will be stable and identical in every batch.

- Effectiveness

  The medicine achieves its intended effect on patients.

Quality Management System (QMS)

There are two major division in a Quality Management System:

Quality Assurance (QA)

- QA refers to ALL of the activities undertaken company-wide to guarantee that an organization produces a product of expected and stated quality.

Quality Control (QC)

- QC refers to efforts taken to test both the components that go into making a product and the final product itself to ensure that requisite standards are met.
- QC work is mostly done in the laboratory.

Relationship of GMP, QA and QC



Vocabulary

GMP - **Good Manufacturing Practices** are defined by the FDA as systems to assure proper design, monitoring, and control over manufacturing processes and facilities in pharma and other FDA-regulated industries. These systems are designed to help organizations assure drug products are the correct identity, strength, purity, and quality.

FDA – **Food and Drug Administration** - The FDA regulates the production and sale of pharmaceutical drugs, medical devices, food, tobacco and cosmetics. The FDA enforces GMP.

QMS – **Quality Management System** - A management system to direct and control a pharmaceutical company with regard to quality.

QA – Quality Assurance - QA refers to the activities undertaken to guarantee that an organization produces a product of expected and stated quality. The QA group, required by law, oversees operations and procedures to guarantee that components used in the manufacture of products and the final products themselves meet the required quality standard.

QC – Quality Control - QC refers to efforts taken to test both the components that go into making a product and the final product itself to ensure that requisite standards are met. The QC group is responsible for performing actual tests about the properties of the entire batch of product from which the sample was taken.