

Process Validation

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What is Process Validation?

- Collection and evaluation of data to establish scientific evidence that a process is capable of consistently delivering quality product
- Proactive
- Protects public health



How is it used in other industries?

- Food and Drugs
- Examples
 - Milk – Pasteurization
 - Military – Risk and collection of scientific data through testing protocols

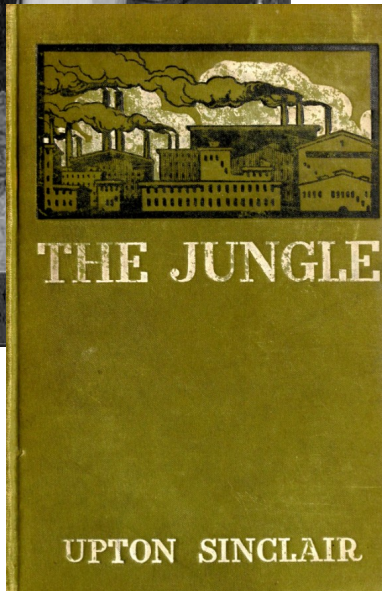


HOW DID WE GET HERE?

What are some of the historical precedents that make Good Manufacturing Practices (GMPs) and Process Validation so critical?



265 Splitting backbones and final inspection cooler, Swift & Co., Chicago, U.S.A. c.



FEDERAL FOOD, DRUG, AND COSMETIC ACT

[As Amended Through P.L. 114-255, Enacted December 13, 2016]

CHAPTER I—SHORT TITLE

SECTION 1. [21 U.S.C. 301] This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

CHAPTER II—DEFINITIONS¹

SEC. 201. [21 U.S.C. 321] For the purposes of this Act—²

(a)(1) The term “State”, except as used in the last sentence of section 702(a), means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term “Territory” means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term “interstate commerce” means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term “Department” means the Department of Health and Human Services.

(d) The term “Secretary” means the Secretary of Health and Human Services.

(e) The term “person” includes individual, partnership, corporation, and association.

(f) The term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g)(1) The term “drug” means (A) articles recognized in the offi-

The Pure Food and Drug Act of 1906 prohibited the sale of misbranded or adulterated food and drugs in interstate commerce and laid a foundation for the nation’s first consumer protection agency, the Food and Drug Administration (FDA).

HOW DID WE GET HERE?

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2012 Framingham, MA

New England Compounding Center (NECC)

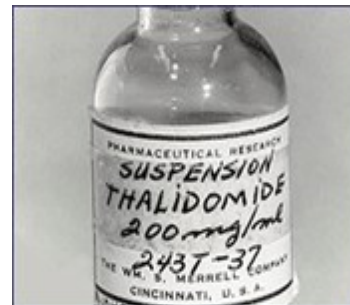
Contaminated steroid injection containing fungal meningitis

- ▶ 800 Sickened
- ▶ 76 deaths
- ▶ 14 NECC employees federally charged
- ▶ \$200M settlement
- ▶ 2013 Drug Quality and Security Act



1937 Sulfanilamide poisoning

- ▶ 240 gallons
- ▶ 100 deaths in 15 states



1957 Thalidomide

- ▶ 10,000 worldwide cases
- ▶ 50% mortality rate

RECENT EXAMPLES OF GMP CRISIS

Westword SUPPORT US *The Independent voice of Denver since 1977*



Jacqueline Collins

In Random Mold Tests at 25 Denver Dispensaries, 80 Percent Fail

THOMAS MITCHELL | OCTOBER 30, 2019 | 10:07AM



Hey, who pre-licked my pre-roll? A cautionary tale in the time of COVID-19

Bruce Kennedy
August 18, 2020



Outbreak of Lung Injury Associated with the Use of E-Cigarette, or Vaping, Products

Español (Spanish)



- For Healthcare Providers
- For Health Departments
- Frequently Asked Questions
- Resources
- Digital Press Kit

CDC, the U.S. Food and Drug Administration (FDA), state and local health departments, and other clinical and public health partners are continuing to monitor e-cigarette, or vaping, product use-associated lung injury (EVALI).

Unusual association of diseases/symptoms

CASE REPORT

Cryptococcal meningitis in a daily cannabis smoker without evidence of immunodeficiency

Bryan B Shapiro,^{1,2} Rebecca Hedrick,² Brigitte C Vanle,² Courtney A Becker,³ Chris Nguyen,³ David M Underhill,³ Margie A Morgan,⁴ Joel D Kopple,^{5,6,7} Itai Danovitch,² Waguih William IsHak^{2,6}



| WELLNESS |

Colorado Issues First Marijuana Recall Over Heavy Metal Contaminants

THOMAS MITCHELL | OCTOBER 9, 2020 | 8:00AM

Process Validation and Labs/ Final Product Testing



**Test smarter not
harder!**



Opportunit

Provide scientific knowledge and expertise to OK growers and processors –
Reduce failures and improve processes.



Commercial Food

and Ag developed positive relationships with third-party labs.



How Process Validation can be Applied to the Cannabis Industry

Growers and Processors assess, document and test throughout their production process to ensure processes are repeatable and final products are safe for consumption.

Examples

- Processor ensures its concentrate purging methods consistently remove contaminants.
- Grower ensures its pesticides do not contain banned pesticides.



Needed Regulatory Tools

OMMA will formulate standards and other guidance to industry as to how to achieve process validation. May include:

- Documenting process controls
- Testing entire process
- Final product testing
- Evaluating risk
- Documentation Procedures
 - Batch records
 - Material changes
 - Deviations



Needed Regulatory Tools

- Records
 - Validation records
 - Test results
 - Standard operating procedures
 - Batch records
 - Reports evidencing process validation
- (Seed-to-Sale Tracking)
 - Metrc can already track process validation
 - Shows product testing status





Benefits to Businesses and Patients

Businesses

- Product and employee safety
- Decreased chance of batch failure
- Reduced liability
- Lower costs

Patients

- Higher quality product
- Lower costs



How Process Validation Combats the Illicit Market

- Bad actors and illicit operators will not invest in process controls and extra testing.
- Compliant businesses will produce better product for less cost.
- Market shift to enable good actors to succeed, while removing illicit actors through market competition.



Current Impact on Compliant Businesses

- Apothecary Farms and Apothecary Extracts
 - Started employing in 2019
 - Currently 70+ employees in OK – full benefits
 - Largest private employer in Beggs
 - Invested over \$3 million in operations
 - At a competitive disadvantage to bad actors and illicit operations. Our cost to do business is greater than theirs.
 - **\$4.2 million on testing for processing operations** (48% of total operating budget)
 - **\$700,000 on testing for growing operations** (37% of total operating budget)
 - These costs could be reinvested in our employees and community.



Thank you!

Questions? Please
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