

***Intro into
GLP and GMP***

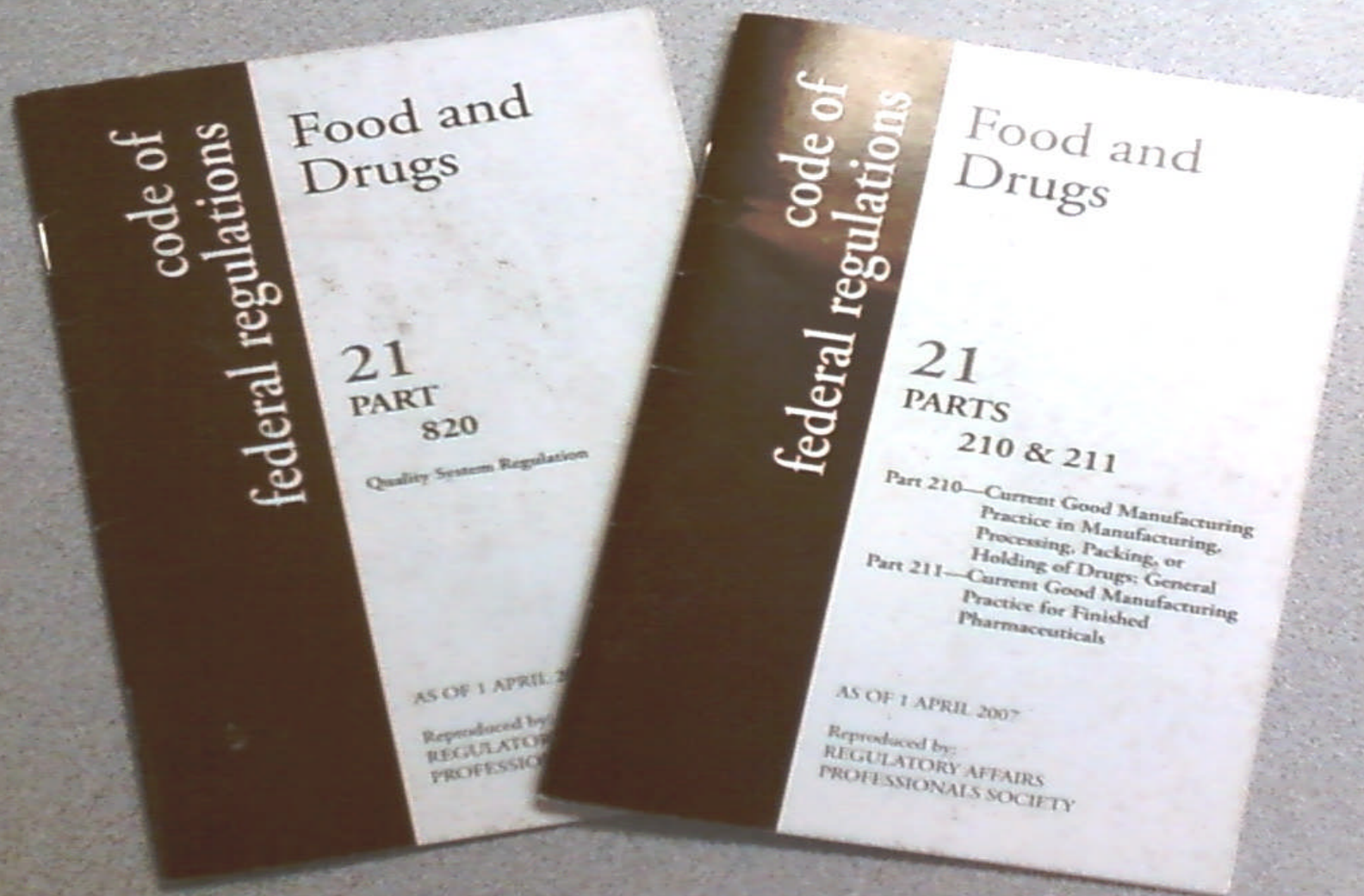
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Academic Research

- **Law** – a generalization of observed behaviors
- **Hypothesis** – a tentative explanation of a given set of data that is expected to remain valid after future observation and experimentation
- **Theory** – a set of tested hypothesis that gives an overall explanation of some natural phenomenon or phenomena

“there is no proof or absolute truth in science”

CFR



Research

By FDA standards . . .

- A VERY uncontrolled, undisciplined activity!!!
- Innovation is the key

Development

By comparison . . .

- Much more disciplined
- GLP and cGMP are considerations
 - GLP - for formal testing and FDA submissions
 - GMP - for pilot production and scale up manufacturing

Manufacturing

Must be even more disciplined . . .

- cGMP takes priority
- QC is an important driver!

Productization stages

(medical device)

Research

Development

Manufacturing

feasibility
concept

plans
input
SOPs

output
GLP
DHF

GMP
change

GCP
validations
clearance
transfer
launch

reviews
verifications
compliance
risk

510(k) clearance letter from FDA

..we have determined the device is *substantially equivalent* (for the indications for use stated in the enclosure) to the legally marketed predicate device.....

A *substantial equivalent* determination assumes *compliance* with the *Current Good Manufacturing Practice requirements*, as set forth in the *Quality System regulation (QS) for Medical Devices: General Regulation (21 CFR Part 820)* and that, through *periodic QS inspections*, the Food and Drug Administration (FDA) will *verify* such assumptions. *Failure to comply with the GMP regulation may result in regulatory action.....*