

# Drug Discovery Best Practices

How will the pharmaceutical industry  
change during this decade?

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# Scientists hate “low grade” science

Gordon Binder, Former CEO of AMGEN

Harvard Business Press 2008, Science Lessons, What the business of Biotech taught me about management, Chapter Nuclear Winter

- Discovery (1995)
  - The EPO what was sold at that time (under an license agreement with J&J) was actually a mixture of five EPOs. Each had the same amino-acid backbone but with different carbohydrates.
  - Each EPO had the same stimulatory effect on bone marrow; but to varying degrees: the protein with the most carbohydrate was most most effective.
- Evaluation (1995)
  - EPO was extraordinarily good. 99% of patients responded to it with no adverse side effects.
  - The only benefit of a reconfigured EPO was its increased molecular weight; it would be more active and stay in the body longer.

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- AMGEN Scientists’ Proposal (1995)
  - They dismissed the proposal of developing a more active, longer-lasting EPO.
  - They regarded prolonging a drug in the bloodstream as “**low grade” science**.
  - Making a wholly new discovery was “genuine” science in a real-men-don’t-eat-quiche way.
  - And: The scientists who came up with the discovery had “defected” from R to D.

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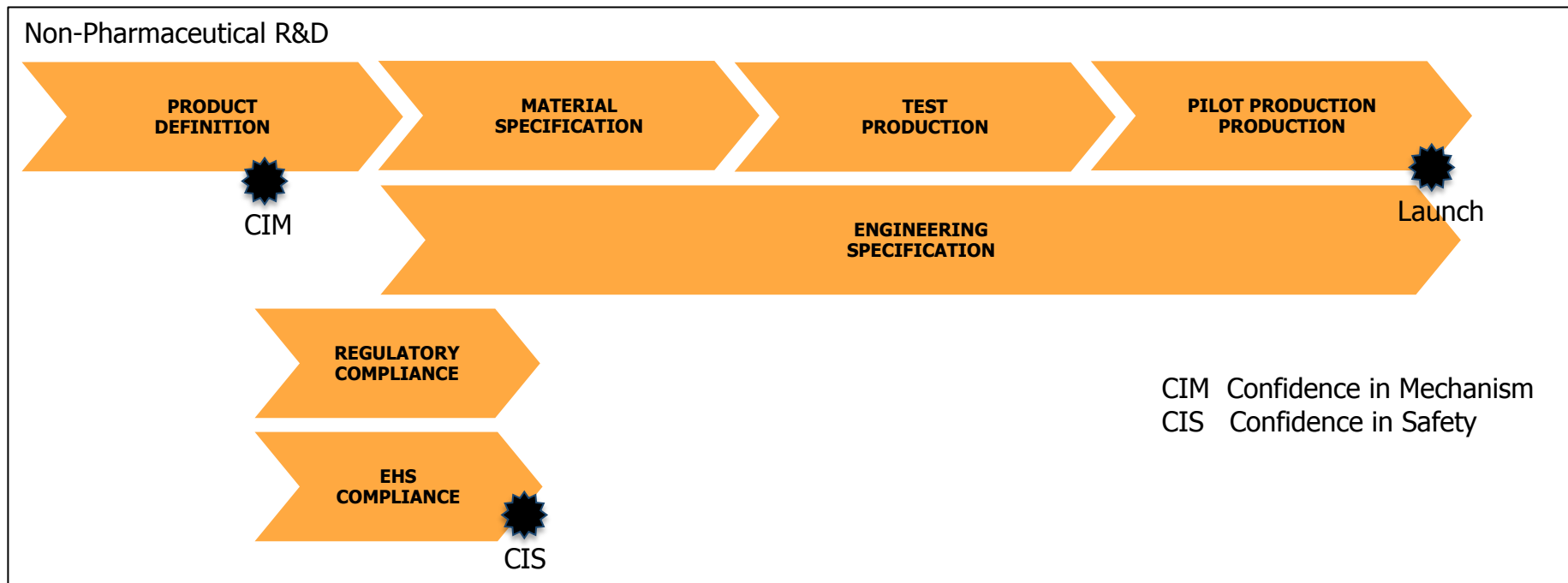
Harvard Business Press 2008, Science Lessons, What the business of Biotech taught me about management, Chapter Nuclear Winter

- AMGEN CEO & President decide against scientists (1995)
  - Long-lasting EPO would improve the quality of patients life (one needle stick instead of many sticks per week).
- The Result: An AMGEN success story
  - More than 100 molecules with additional carbohydrates were engineered and tested.
  - Finally, Darbepoetin alfa (Aranesp) was developed with a substantially longer half-life (1996).
  - Court Panel decided 1998 that Aranesp is a new product and granted AMGEN the exclusive rights on it (which kicked-out J&J and opened AMGEN the EPO markets in USA and Europe).
  - Aranesp reached the market (2001).

# Is Pharmaceutical R&D ... different from R&D in other producing industries ?

Yes –

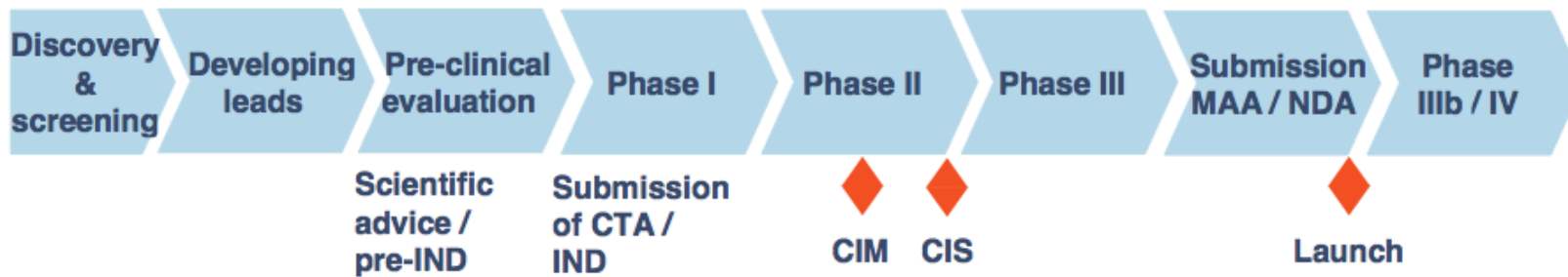
Non-Pharmaceutical R&D is organized as a predominantly parallel development process with in-build iteration cycles. Confidence in Mechanism and Safety is given at earlier stages by using digital engineering/simulation technologies.



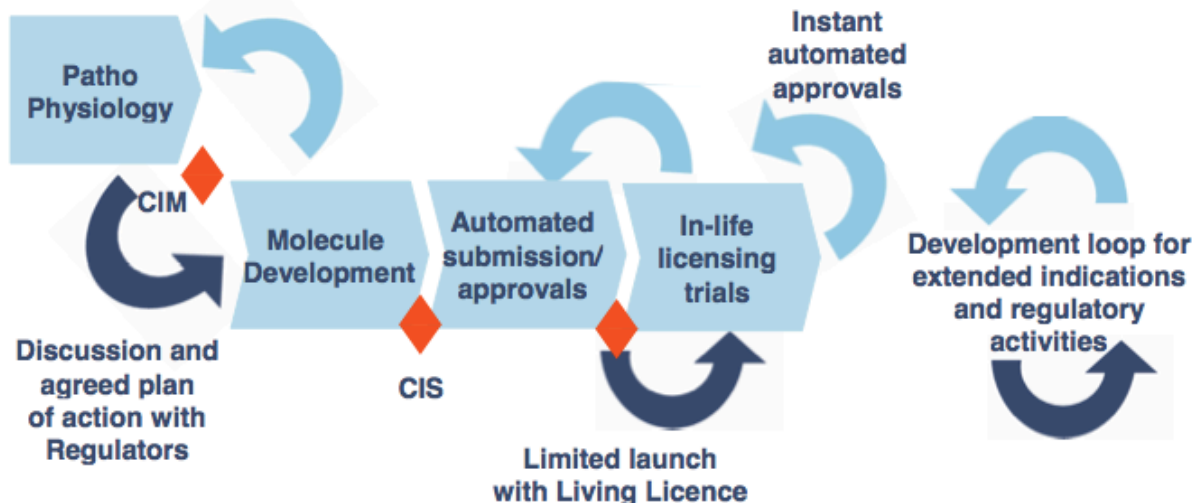
# How will the R&D process look like in 2020?

The PricewaterhouseCoopers projections

## Today – Intensive all-or-nothing regulation



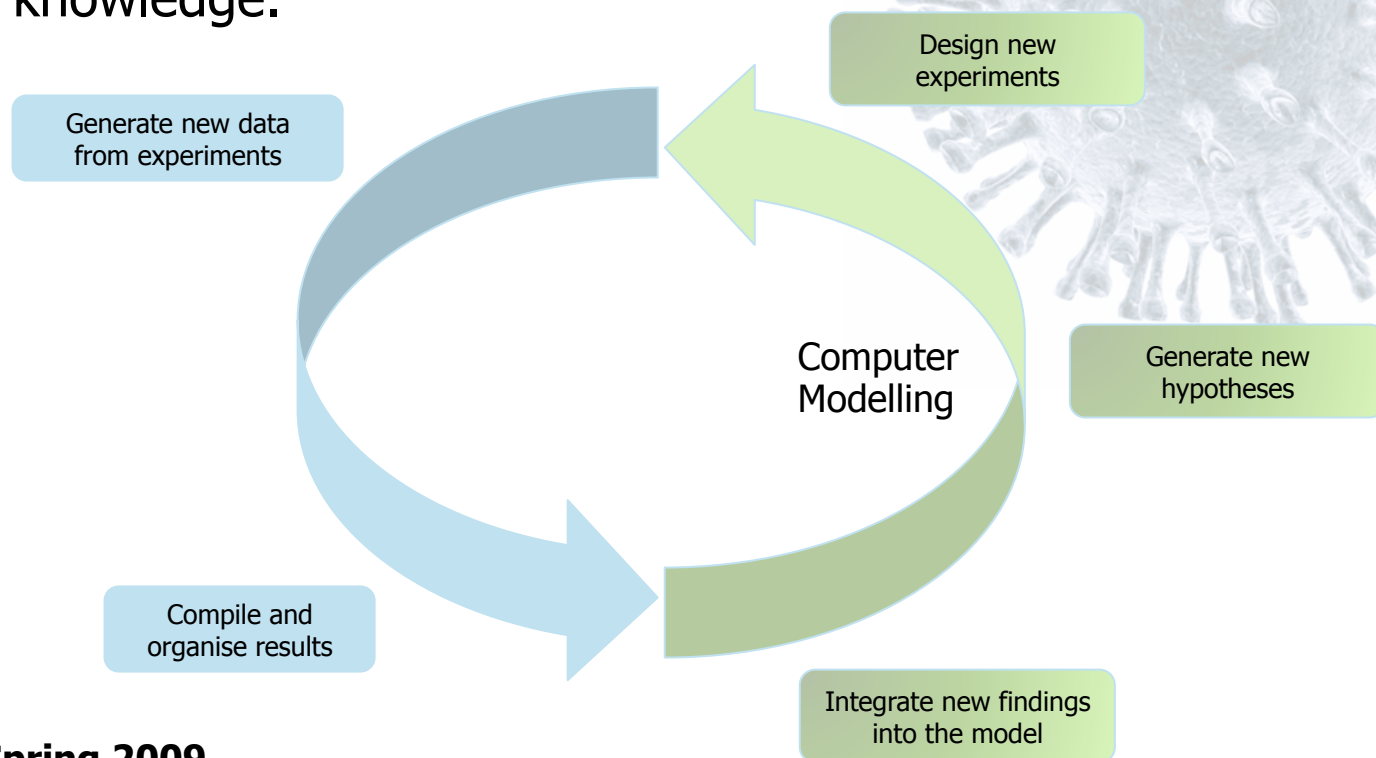
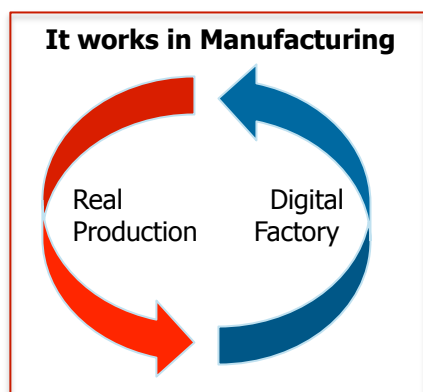
## 2020 – Collaborative, evolving, automated regulation



CIM = Confidence in mechanism  
CIS = Confidence in safety  
IND = Investigative New Drug  
CTA = Clinical Trial Application  
MAA = Marketing Authorisation Application

“The burgeoning volumes of laboratory data pose more questions than they answer until such time as they can be assimilated as real knowledge.

Modelling can provide the kind of intellectual frameworks needed to transform data into knowledge. “



Gordon Webster  
**Drug Discovery World Spring 2009**  
Biologist flirt with Models

October 2009

# How will the Pharma Industry Change?

- Pharma has to deliver products that the market wants in a changed world
  - Science is leading the industry towards specialists therapies and personalized medicine.
- Pharma must become more efficient and innovative
  - Adopt best R&D and manufacturing practices from other industries.
    - Parallelization of development and regulatory processes with in-build iteration cycles
  - Invest in standardization & integration
    - SiLA (Standardization in Lab Automation)
    - Pistoia (Enterprise data standards, ontologies and web-services)
  - Provide models to transform data into knowledge

# Many Thanks for Your Attention



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