



Developing the Perfect Plant: A high tech approach to supporting low cost bioprocessing plants

Robert Gamber

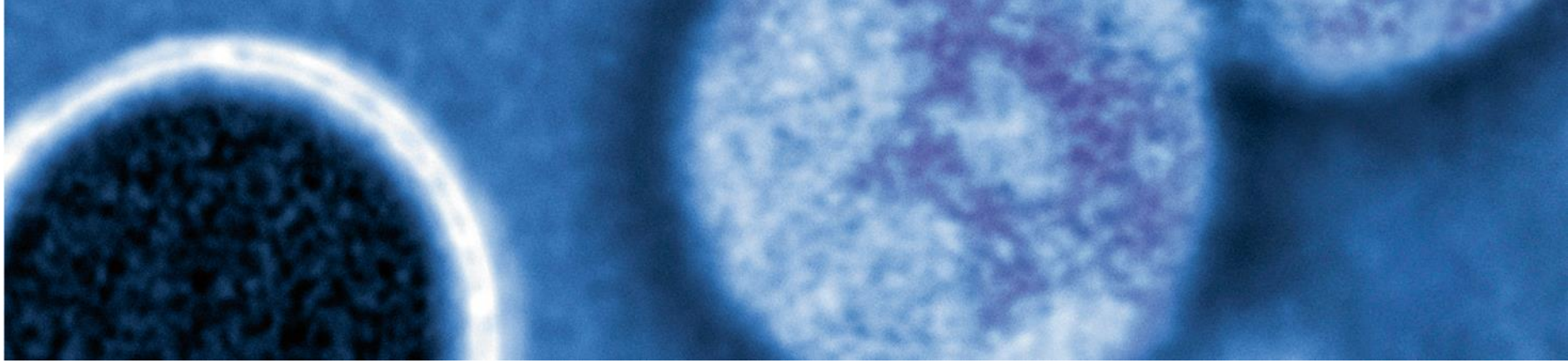
Principal Engineer – Platform Lead

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Our Mission

To serve patients





Amgen
Biotechnology
Pioneer

One of the first
biotechnology companies
successfully **discovering,**
developing, and making
biologic medicines



Amgen's Therapeutic Areas

- Bone Health
- Cardiovascular
- General Medicine
- Hematology/Oncology
- Inflammation
- Nephrology

Our Products

For additional information about Amgen products, including important safety information, please visit www.amgen.com.

EPOGEN[®]
(EPOETIN ALFA)
RECOMBINANT

NEUPOGEN[®]
(FILGRASTIM)

Aranesp[®]
(darbepoetin alfa)

 **Neulasta[®]**
(pegfilgrastim)

 **Enbrel[®]**
etanercept

Sensipar[®]
(cinacalcet) Tablets
30mg - 60mg - 90mg

 **Vectibix[®]**
(panitumumab)
Injection for IV Infusion

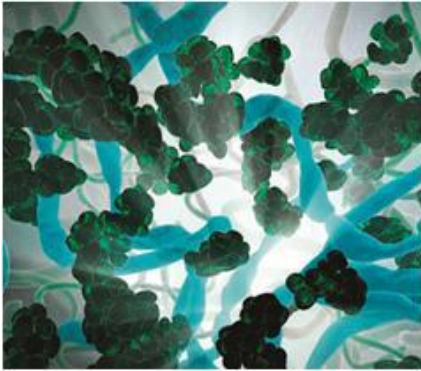
Nplate[®]
romiplostim

 **prolia[®]**
(denosumab) injection

XGEVA[®]
(denosumab)

Next Wave of Innovations

We're leading the industry



Driving

Cutting-edge research
and development



Developing

Therapies in multiple
modalities



Advancing

The science of
biotechnology
manufacturing

Leader

in Biotechnology Manufacturing



Clear Strategy

To innovate and grow

Advance treatment of serious illness

Invest in R&D across wide range of therapeutic areas

Reliably manufacture with the highest quality and lowest cost

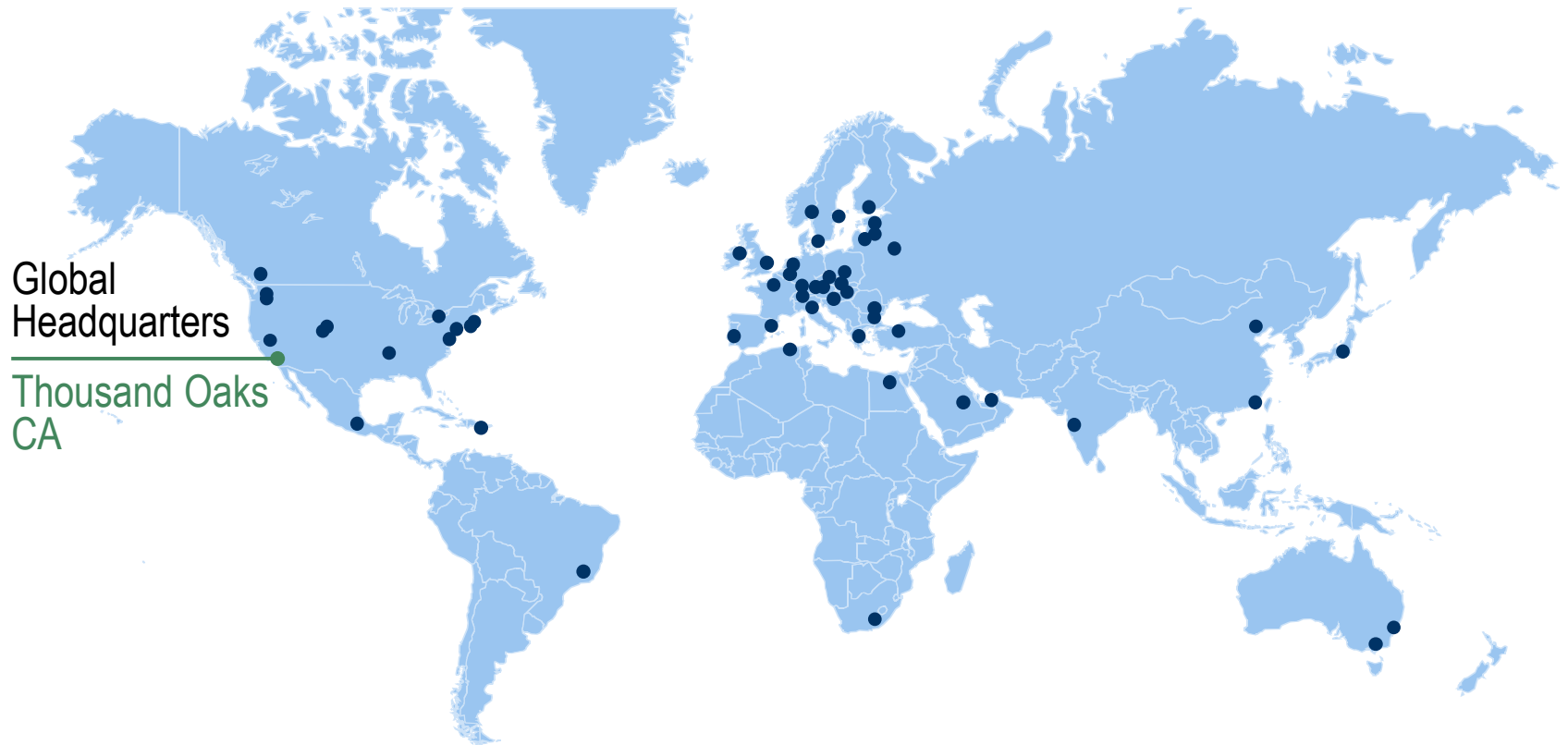
Expand our operating footprint

Manage our cost structure

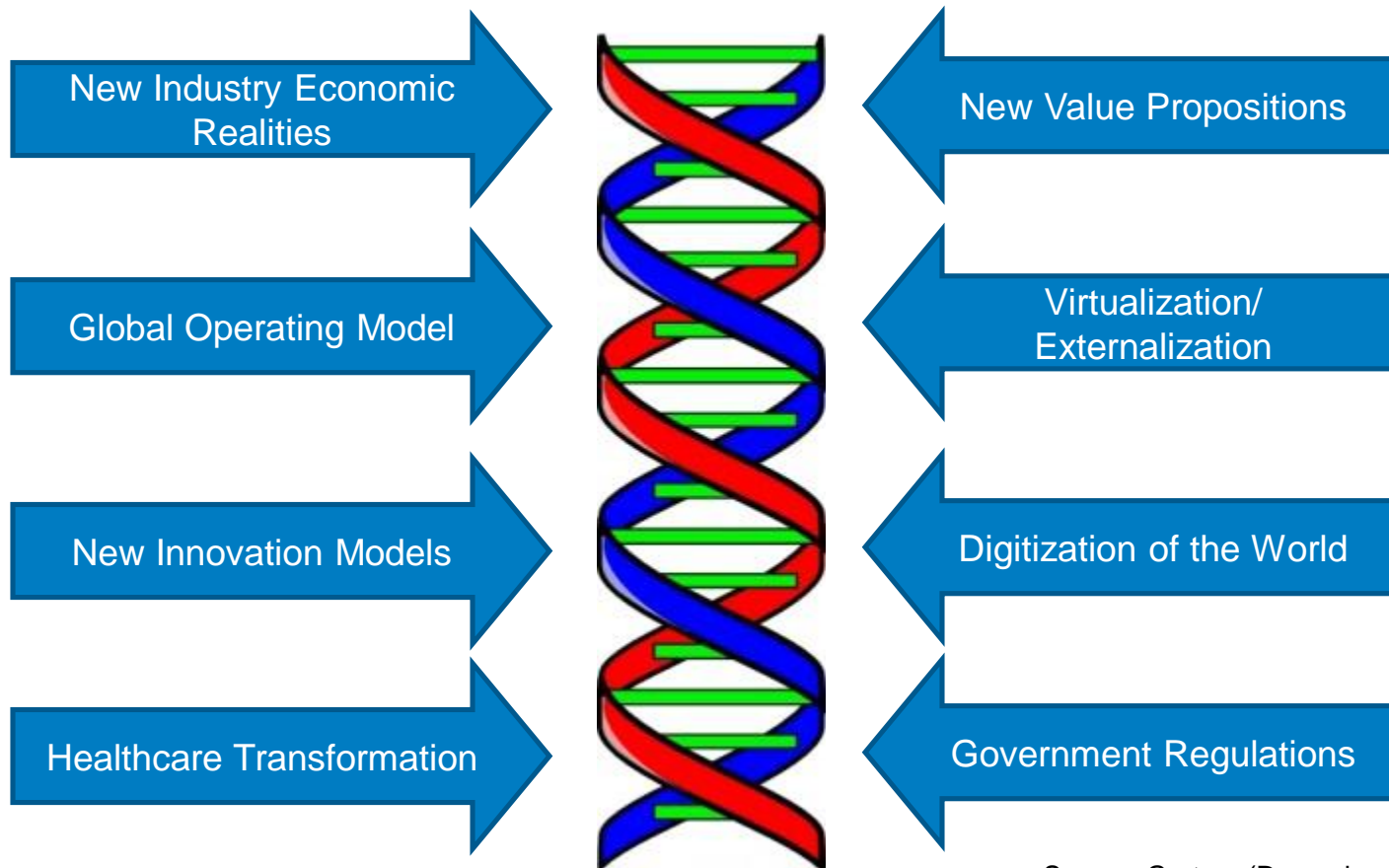
Return significant capital to shareholders

Sustain a strong social architecture

Extending Our Reach to Help More Patients



Business Drivers Influencing Bio-Pharmaceutical Manufacturing



Source: Gartner (December 2012)

This new reality is driving the need to reassess how products are manufactured via more cost effective means.

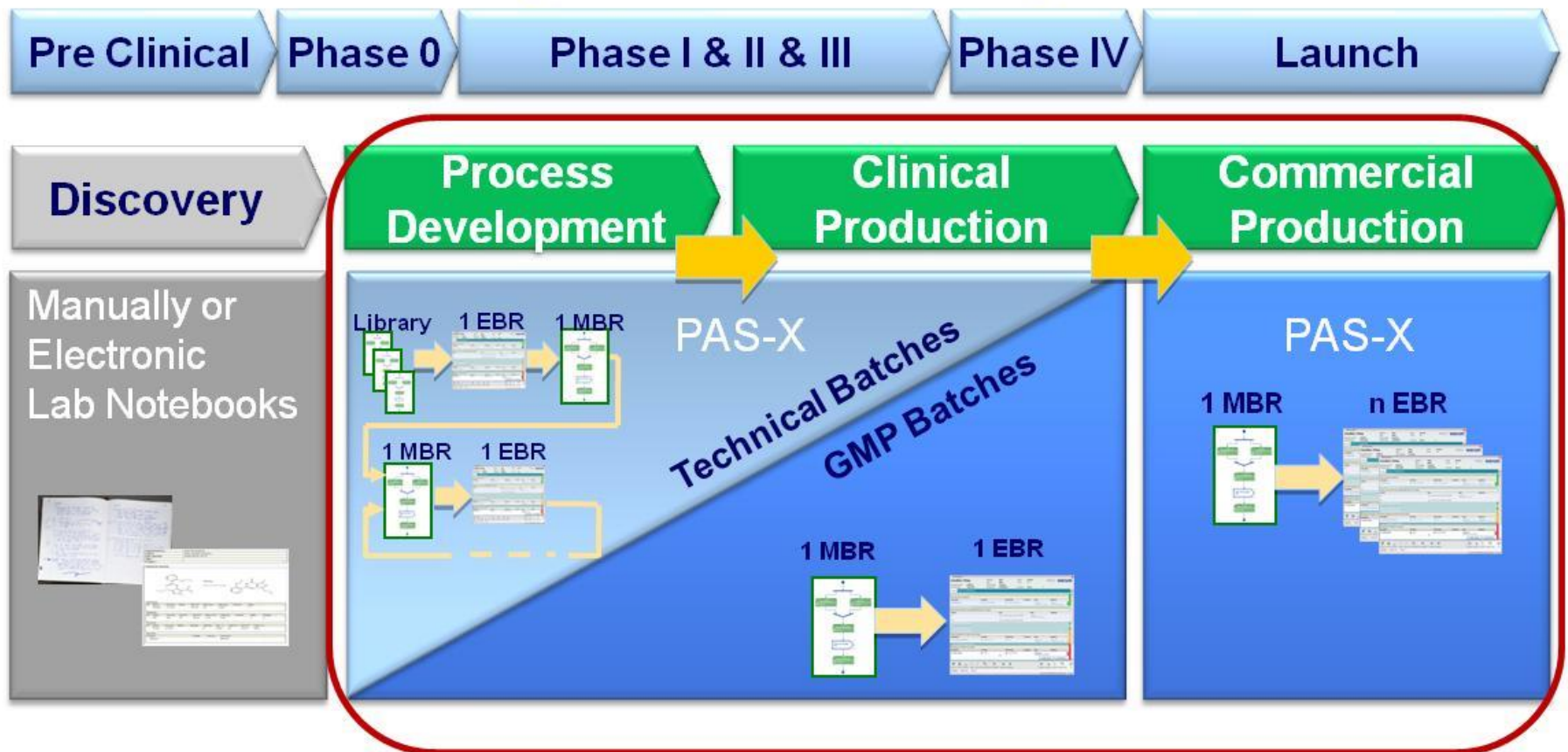
Goals for Future Manufacturing Plants

Accelerate time to market while reducing variability and risk

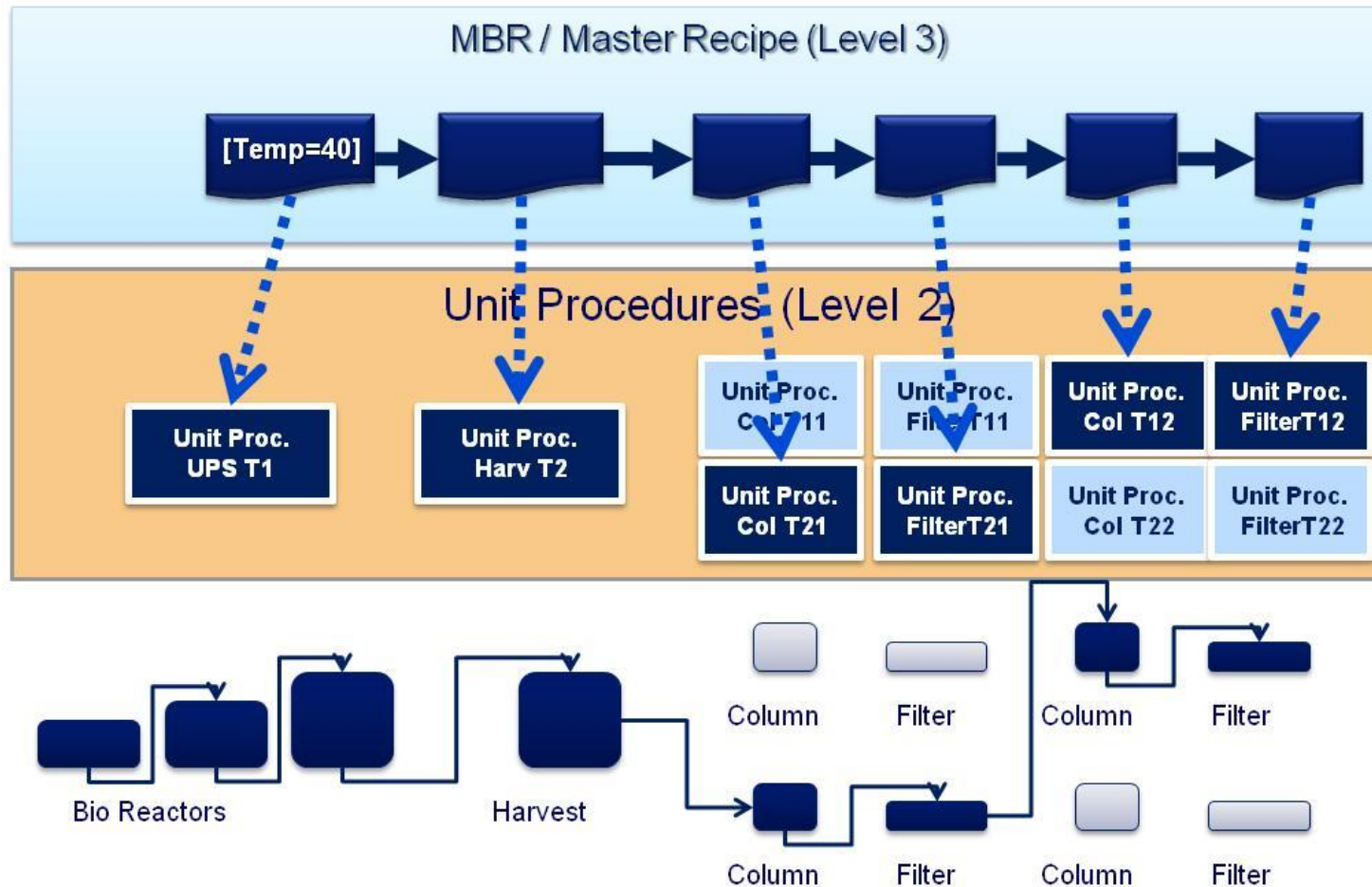
- Multi-purpose Equipment
 - Standard modular phases and unit operations will be used to support equipment
 - Parameters for operations will vary according to product
 - Combination and sequencing of modular unit operations, and/or phases will vary according to product
- Multi-product Facilities
 - Rapid change-over between products
 - Rapid introduction of new products
 - Master Recipes must:
 - Cascade from Clinical to Launch to Commercial Manufacturing
 - Be more streamlined and flexible

Increasing the scope of control facilitates efficient transfer of products through the commercialization process

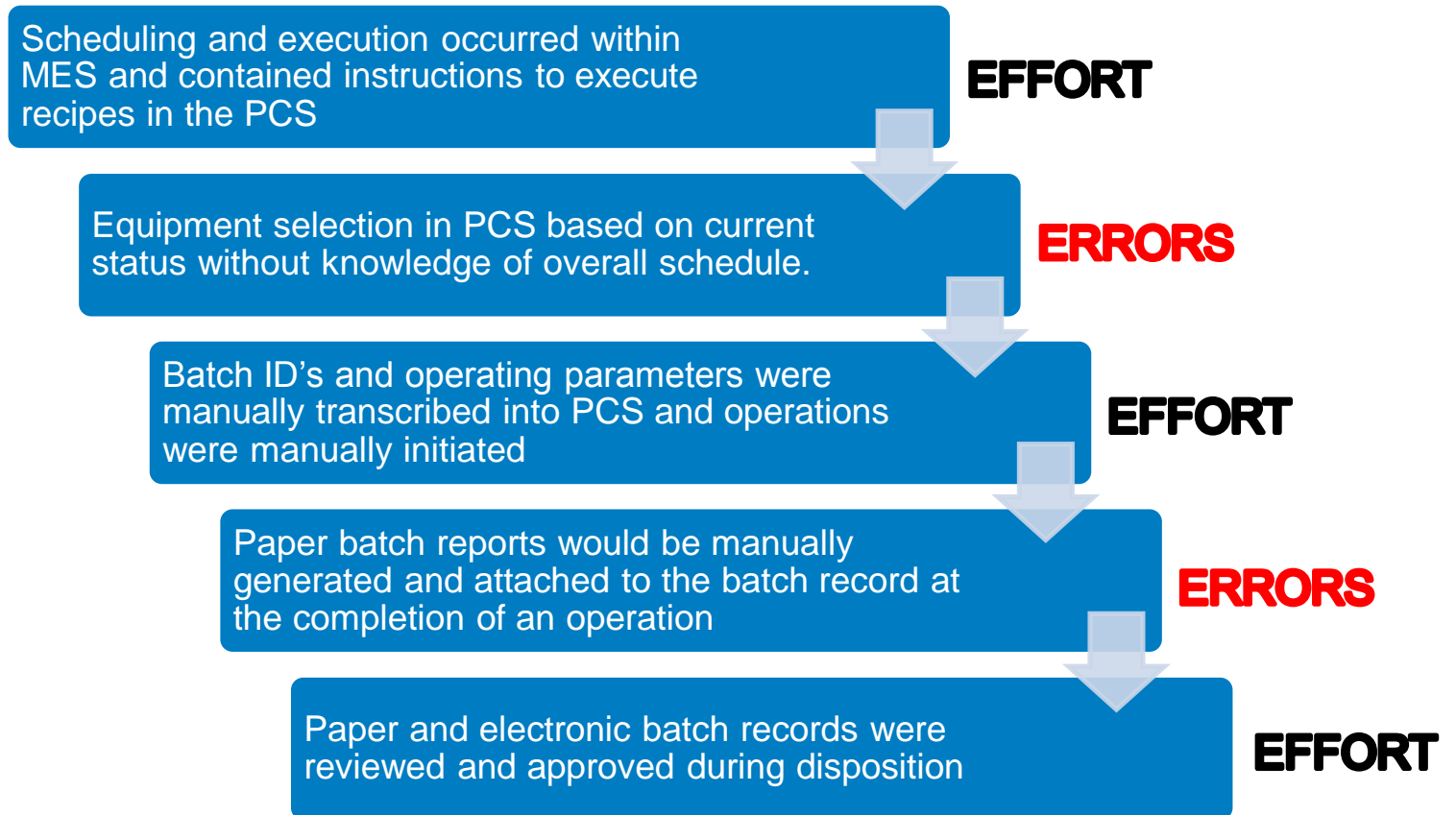
Development Phases of a Drug



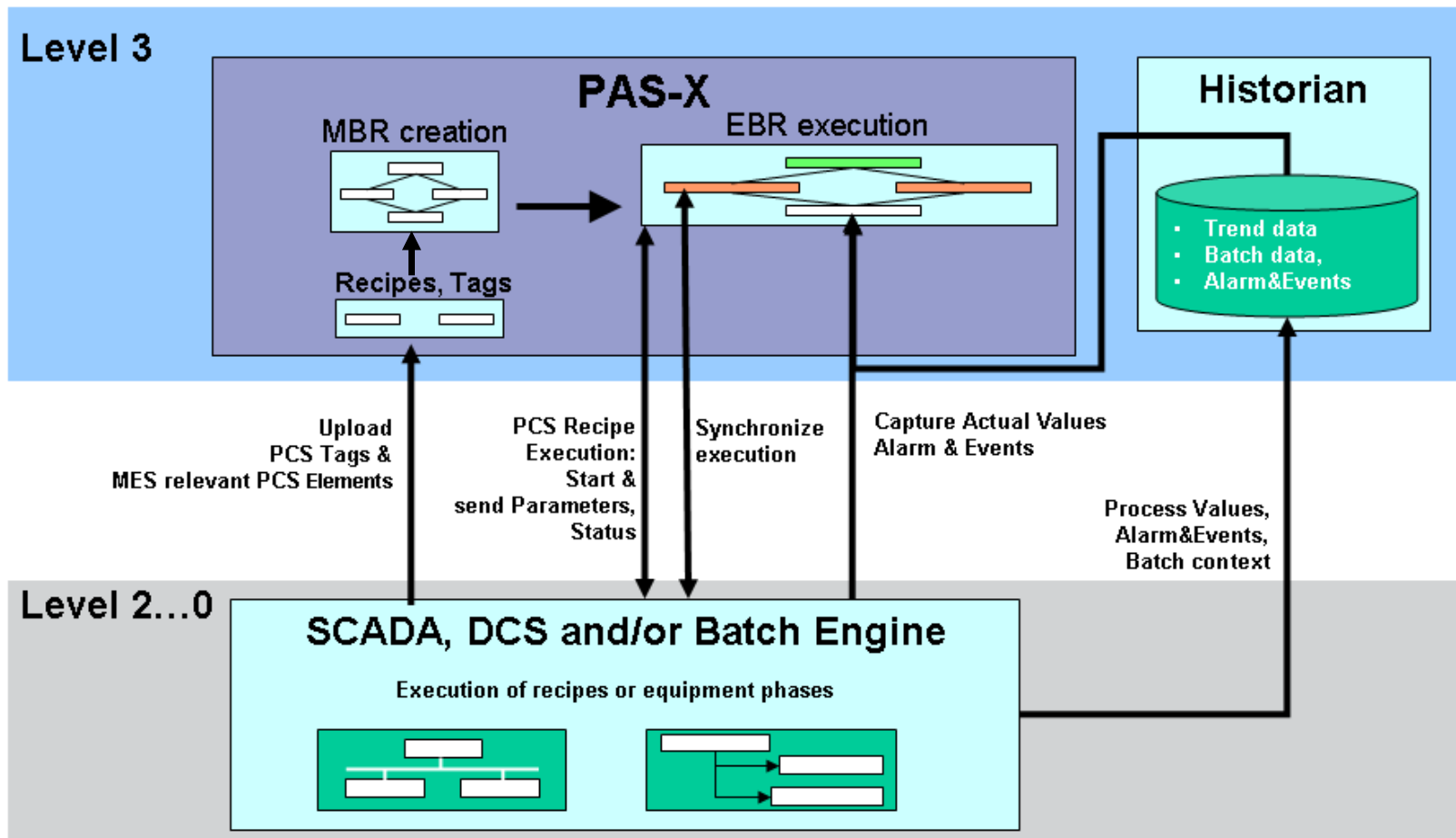
Flexibility is achieved by leveraging L3 product based MBR's that use L2 unit specific procedures



Historically decoupled systems were inefficient and prone to errors



Integration of L2 & L3 systems provides flexibility while reducing errors and improving efficiency



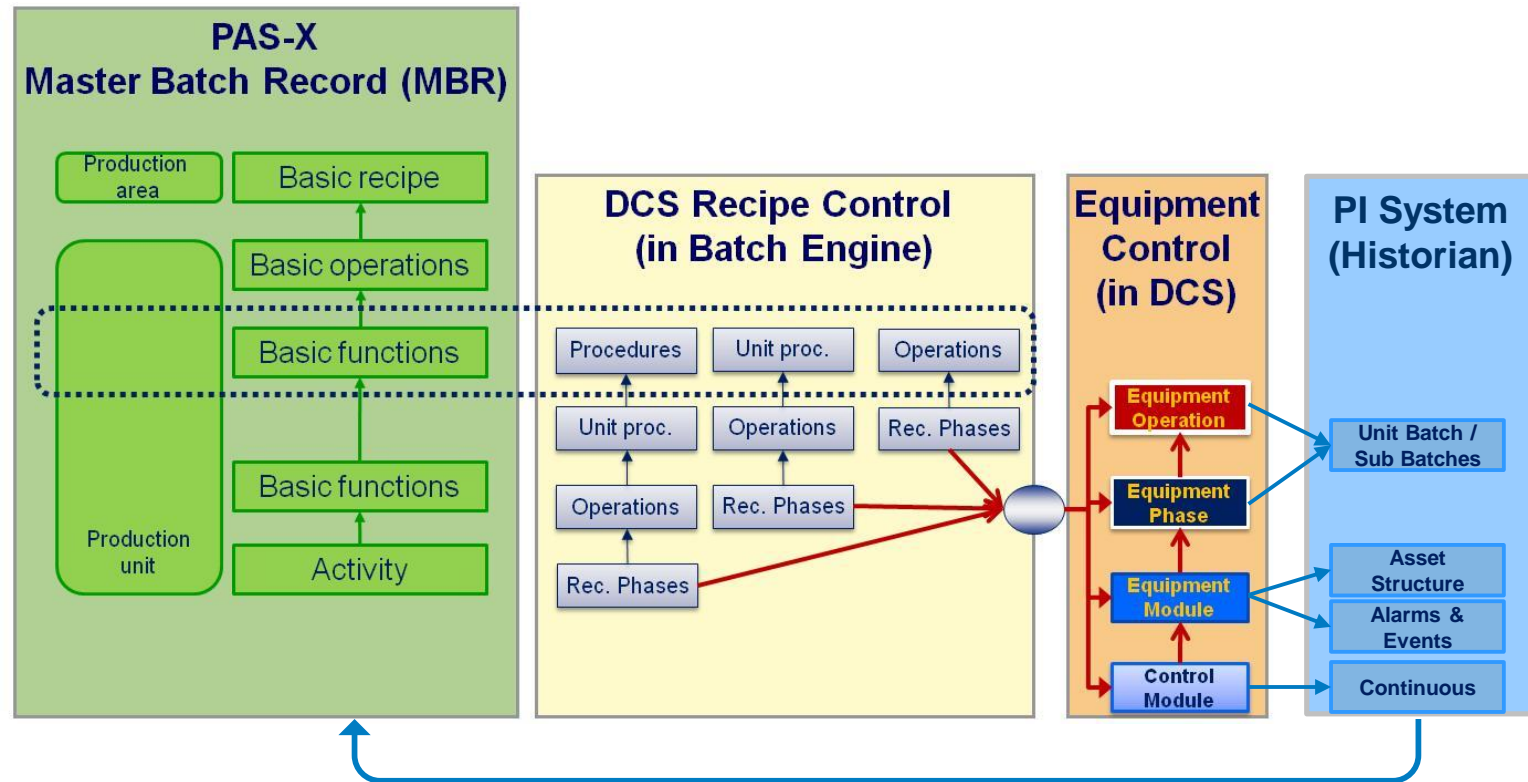
Integrated Environment

Each system operates within its domain and exchange data to allow other systems to execute seamlessly

- MES dictates production execution and gathers data to be able to assess product quality
- PCS executes detailed process steps and controls equipment performance
- Historian collects and organizes relevant data for the executed process

Systems remain lightly coupled to ensure business continuity.

Harmonization is achieved by consistently applying S88 across system boundaries



Summary

- Modular approaches to system design provide for greater flexibility
- Consistent application of systems across the commercialization cycle and use of standards speeds delivery
- Significant value is achieved by integrating L2/L3 systems in a lightly coupled manner