NIBR Exploratory
Immuno-Oncology

Designing technologies to meet the manufacturing needs of new regenerative therapies

Rodney L Rietze, *PhD*
Bioprocess Innovation and Strategic Development
Exploratory Immuno-Oncology
Novartis Institutes of Biomedical Research

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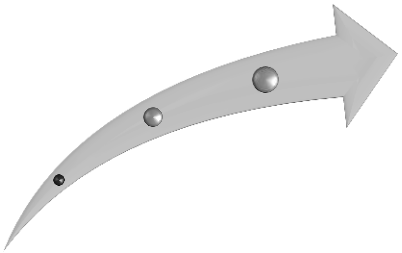
Critical role of automation in manufacturing

Key to achieving a safe, robust, reproducible and cost-effective therapy

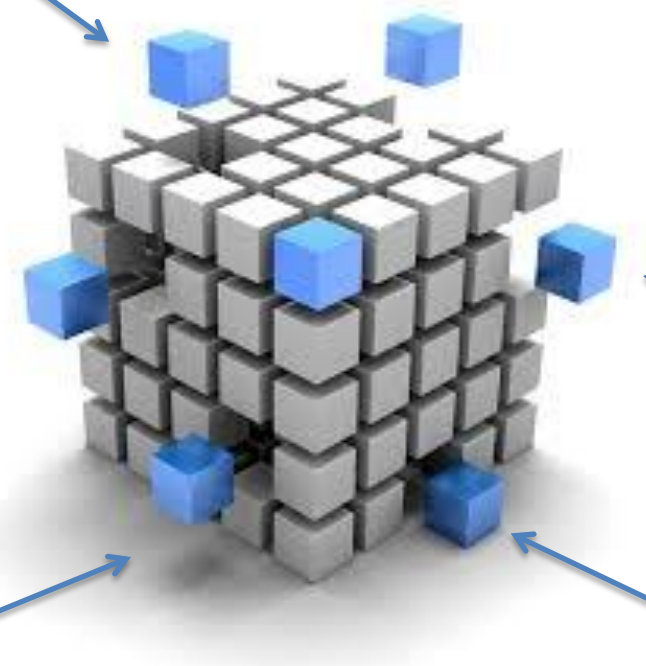
Process Characterization and Development

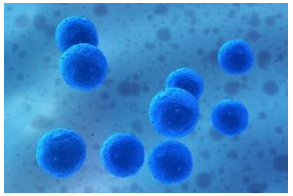
Product, Process and Device IP



Robust Pipeline

Next Generation Technology and Devices

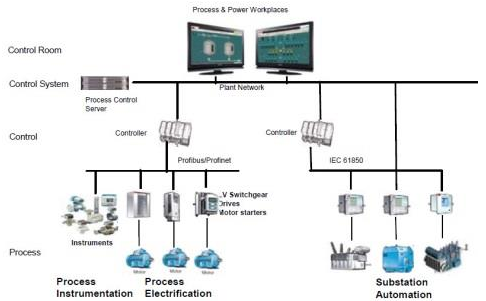




Improved Products

Automation
Process & Analytics

Automation Provides
Lower variability (risk)
Increase success rate (cost)
Deep process insight (control)



Data Systems & Analysis
Incisive and Rapid IPC/QC

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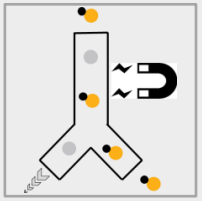
Designing a scalable and robust process

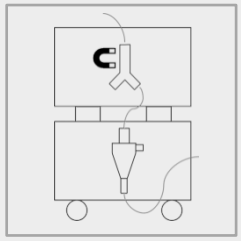
What is the product, how is it defined, produced and (variability) controled?

"small" → "BIG"

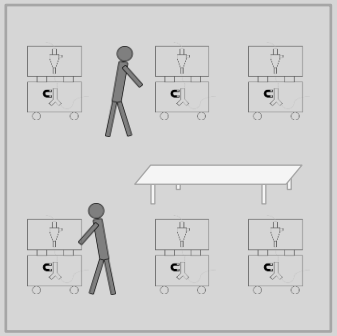
Science



Key Technologies



Automation & Integration



Manufacturing Suite Design & Operation

Enabling Global Supply

- *Off-the-shelf device for immediate value*
- *Emerging technologies for longer term (IP)*
- *Targeting specific Unit Ops lowers risk*
- *Option to rethink analytics*

Automation = Insight

Developing/Integrating

Automating and closing unit operations

- *Closing Unit Ops impacts product flow*
  - *removal of biosafety cabinets*
  - *move out of a clean room*
- *Redeployment/stratification of work force*

Altering Manufacturing

Process flow, footprint, overhead and training

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Roadmap for developing a novel device

Defining the highest needs

- For each unit operation -

Safety
- Contamination risk
- Manual handling error risk
- Impact on product quality

Process
- Duration & throughput
- Time of operator involvement
- Repetition
- Ease of scale-out
- Process step efficacy

Product
- Variability
- Product loss, impact on yield
- Data capture

Cost
- Consumable costs
- Implementation complexity
- Footprint

Delivering the solution

Project Initiation
- Build project team
- Quality & design requirements
- **Formal specifications (URS)**
- Select vendors, send proposals

Partner Selection
- Establish selection criteria
- Agree on device specifications
- Negotiate contract

Prototype and Device
- Design alpha prototype
- Contemplate minor changes
- Factory Acceptance Testing
- Site Acceptance Testing

Integration and beyond

Validation/comparability
- Validation and commissioning
- **Characterization studies**
- Comparability
  - Analytic or Clinical?
- Open change control

Leveraging the device
- Roll out across therapies
- Exploit the technology
- **Push towards research**

Building strategic value
- De-risk new technologies
- **Re-think analytics/IPCs**
- Inform your next steps

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Creating novel platforms from existing tech

FlowSPA³: Flow Sample Prep Automation, Acquisition and Analysis

Samples ---------- **End-to-end automation** ---------→ **Answers**

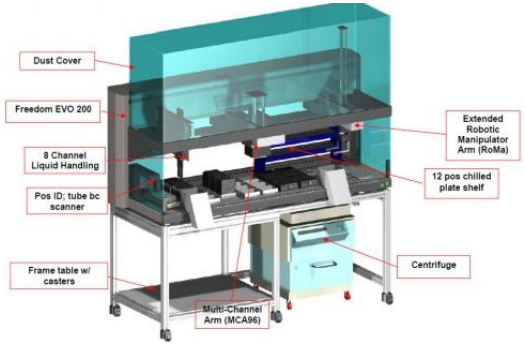
Automation → **Acquisition** → **Analysis**

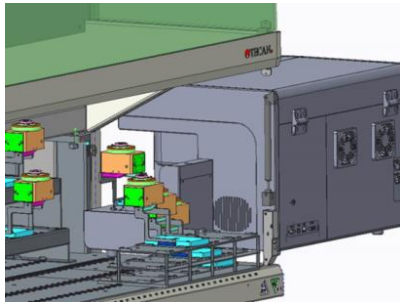
Auditable analytical results

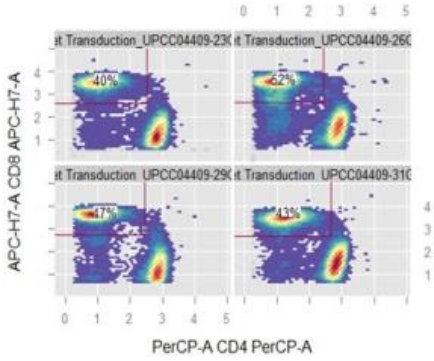
Flexible liquid handling core - across assays

Interface with cytometers, thermocyclers, plate readers

Feed raw data directly into automated analysis pipelines







- Precision in sample processing, reduce operator error, eliminate subjectivity (e.g. gates)
- **The whole is greater than the sum of its parts:**
  - Significant reduction in hands-on time
  - Close Data Integrity gaps end-to-end across analytical assays
  - Guarantee chain of custody end-to-end with auditable logs linking every process step
- **Not primarily about throughput – reducing hand-on time, increasing quality, consistency, and integrity of analytical processes**

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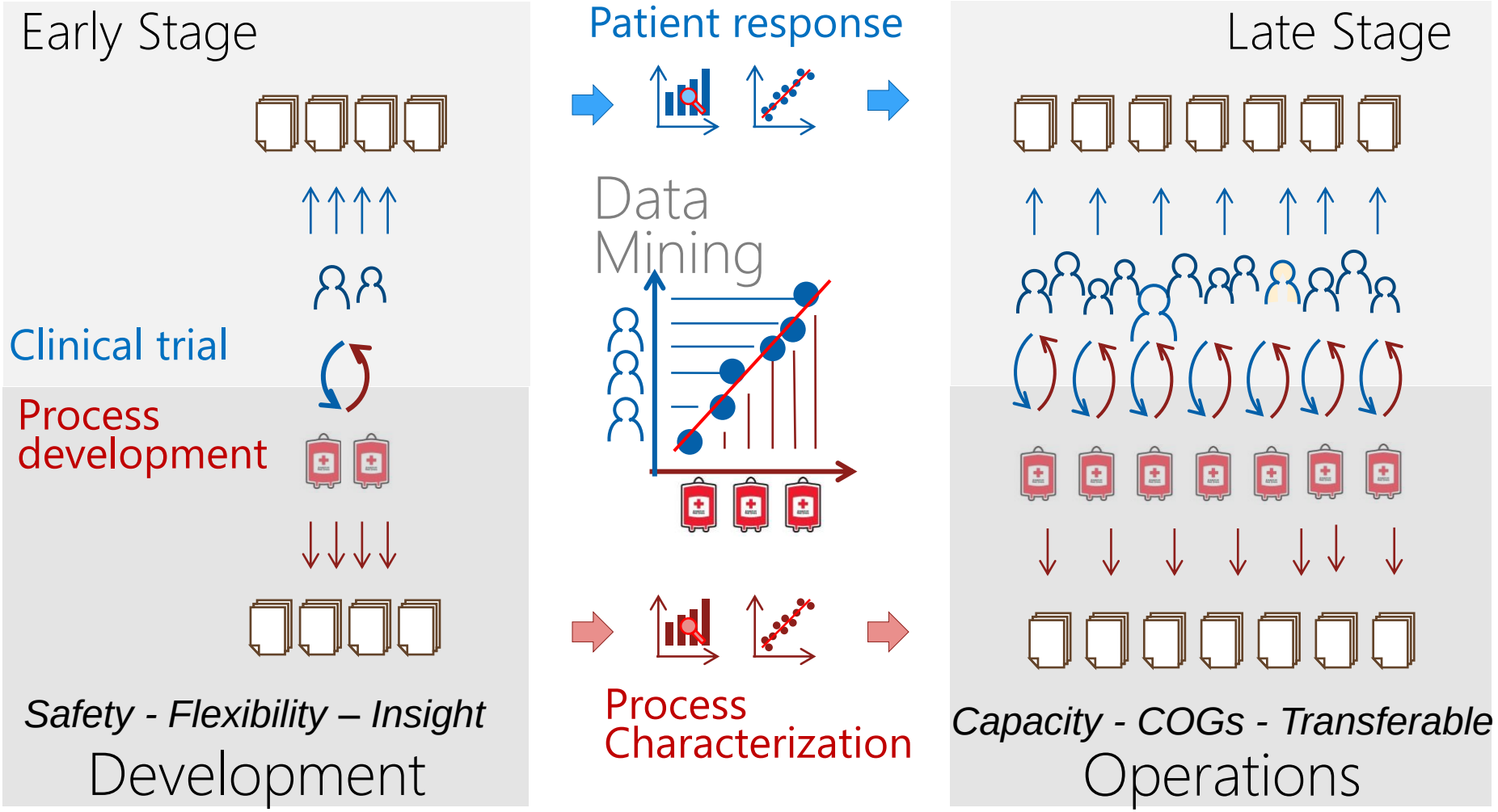
Data driven process design and automation

Generating "meaningful" data to build confidence and drive decisions



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Key trends and progress

- Moving from BLA submission to commercial launch
- Reducing our reliance on the clean-room
  - Closing unit operations
- Reducing product manufacturing timelines
  - Defining starting material (subset selection)
  - Accelerating release timelines (sterility testing)
- Moving towards non-distructive (in process) analytics
- Development of next-generation devices
  - Cryopreservation and thaw
- Connectivity of the patient care pathway

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