Dr. Reddy's Laboratories

Businesses we serve in API & Global Generics

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PSAI

Pharmaceutical Services & Active Ingredients

Customers include generic manufacturers and innovator companies;
Amongst the leaders in supply of generic APIs globally

Global Generics

Global Generics

Finished dosage businesses in distribution-driven as well as doctor-driven markets;
Strategic 'focus' on key large markets → USA, India, Russia & CIS, UK & European Union

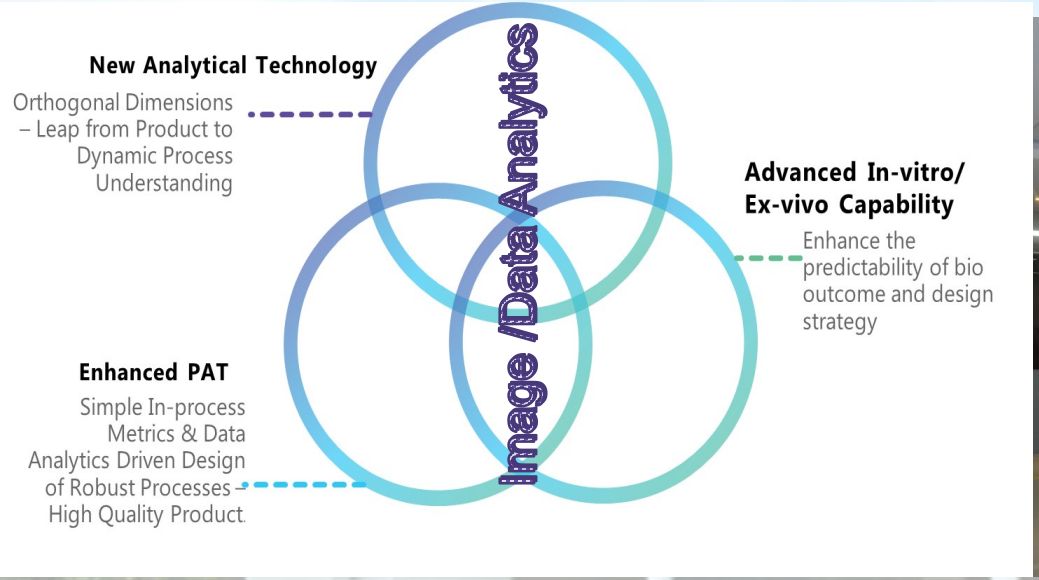
Product Portfolio & Therapeutic Areas

- Active Ingredients
- Polymorph
- Immediate release
- Extended release
- Delayed release
- Orally dissolving tablets
- Nano-particulates
- Particulate Suspensions
- Peptides
- Microspheres
- Liposomes
- Gels & Patches
- Respiratory

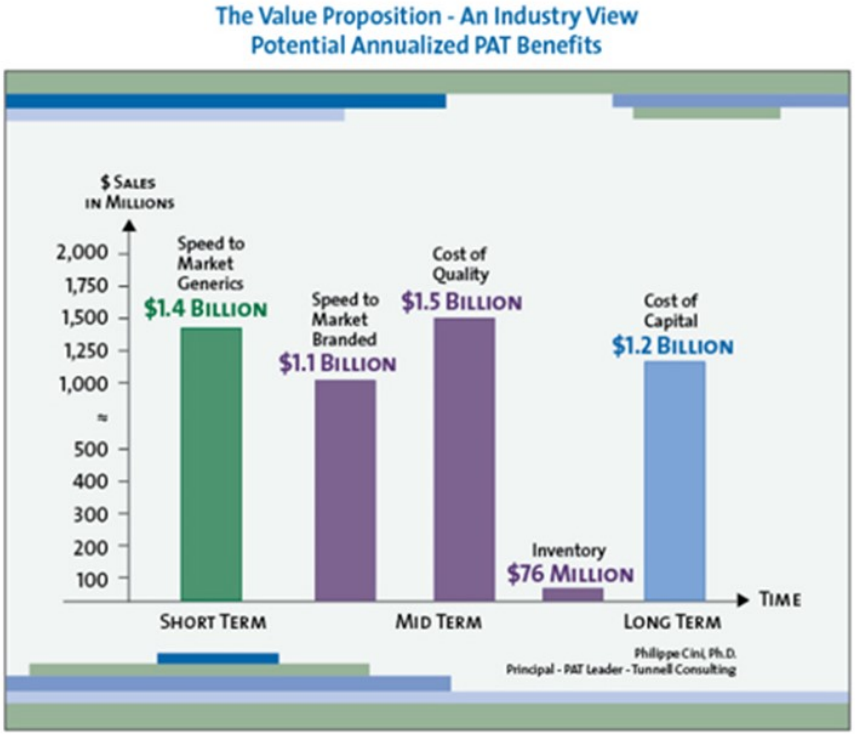
- Gastrointestinal
- Cardiovascular
- Pain
- Anti-infective
- Dermatology
- Diabetes
- Oncology
- Nutraceuticals
- Respiratory
- CNS
- Hematology
- Pediatrics
- Urology
- Opthalmics

Annual Revenue ~ USD 2.4 Billions

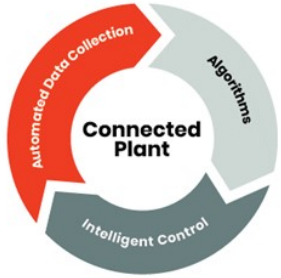
Integrated Product Development Oranization: Advanced Characterization Technology

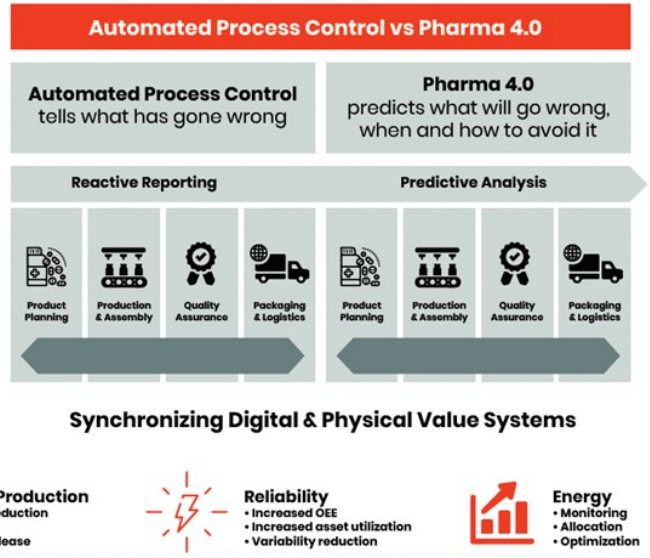


Process Analytical Technologies: Enabling the Factory of the Future



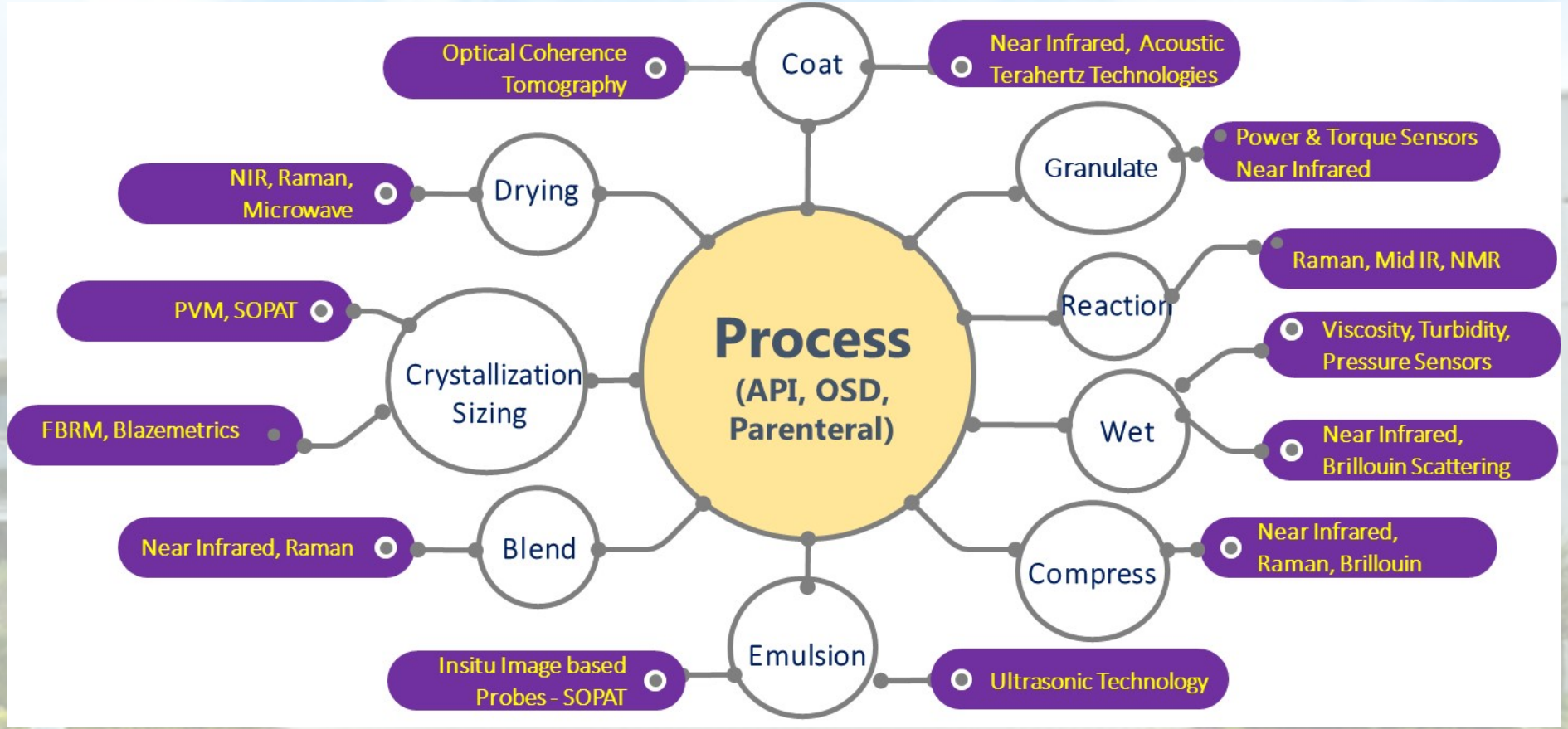
https://www.pharmamanufacturing.com/articles/2006/109/
https://www.quartic.ai/bringing-ai-to-pharma-4-0/





Process analytical technologies (PAT) *is a critical enabler for process automation as well as for continuous manufacturing through real-time understanding and ability to control the manufacturing process, which is consistent with the drug quality system:* ***quality cannot be tested into products; it should be built-in or should be by design***

Process Analytical Technologies



Current Challenges / Improvement Scope

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Blending

- Sensitivity – Low dose API
- Quantitative analysis for Release testing – Calibration Standards
- Interfacing with equipment
- Speed of analysis and model based prediction
- Hyperspectral Imaging

Granulation

- Interfacing challenges for optical probe and fouling
- Image based
- Understanding end point of granulation based on flowability and granule size

Drying

- Multiple solvents
- Probe design and interface
- Impact of solid sate properties and sample heterogeneity
- MS technologies and other new technologies for quantitative analysis

Coating

- Interface for in-line measurements
- Robust correlation models between mass build up and thickness
- Resolution less than 5 microns
- Measurement time /speed of analysis

Compression

- Interface challenge for in-line measurements
- Discipline
- Beam penetration and effective sampling challenges for content uniformity
- Low dose API
- Impact of other physical attributes and their

Particle Sizing

- Interface challenge
- Dealing with highly viscous medium and flow
- Resolution sub microns
- Speed of analysis

Crystallization

- Dealing with highly viscous medium
- Size distribution dynamic range for crystal growth (nm- >100 microns)
- Sensitivity for polymorph detection and other

Reaction Monitoring

- Dealing with highly viscous medium
- Sensitivity and Specificity
- Impurity Control & Monitoring
- Robust Kinetic Model

Wetting

- Dealing with highly viscous medium
- Interfacing challenge for in-line probes
- New technologies
- Multiphase Systems

Model Development Data Systems

- Harmonized Data Architecture across technologies
- Data Analysis Suite
- 21 CFR Compliance

Atanu Sengupta


Dr.Reddy's
Thank You
Atanu Sengupta