RICONPHARMA

Research Innovative Concepts in Pharmaceuticals

Leading Research Through Science, Technology, and Innovation

Pre-formulations → Formulations → Process → Technology → Manufacturing → Submissions

About Us

RiconPharma is an R & D Company, equipped with10,000 sq.ft., state of the art facility in Denville Technical Park, Denville, NJ, USA and Hyderabad, India. Its operations started in October 2008.

RiconPharma Management Team is bringing 65 years of proven and collective experience in Pharmaceutical Development, Manufacturing, and Regulatory Affairs from both Brand/Generic companies.

RiconPharma Management Team has developed and commercialized at least 200 ANDA's in the last 20 years at their previous companies.

RiconPharma Management Team has successfully managed at least 20 Paragraph IV Challenge Products.

Our core competencies are Oral Solids (IR, MR, ODT, and Buccal), Liquids, Topicals (Creams, Lotions, Gels, and Foams), Transdermals, and Parenterals.

Management Team

Raj Devalapalli, President & CEO – Co-Founder
Raj has an MS in Industrial Pharmacy and an MBA in Pharmaceutical Business with 20 years of proven experience in Pharmaceutical Product/Process Technology and Manufacturing. Raj held key responsibility as Global Product and Process Technical Lead for a major product and also led several Technology Initiatives involving Continuous Processing and PAT at Pfizer. Raj held key positions in companies such as Pfizer, Warner-Lambert, Becton Dickinson, and Penwest Pharmaceuticals .

Mukti Gande, CSO – Co-Founder
Mukti has an MS in Pharmaceutical Sciences with16 + years of proven experience in Pharmaceutical Formulation R & D, Sourcing, and Regulatory Submissions. Mukti was instrumental in the development and approval of several ANDA's at CorePharma and Invamed (Sandoz).

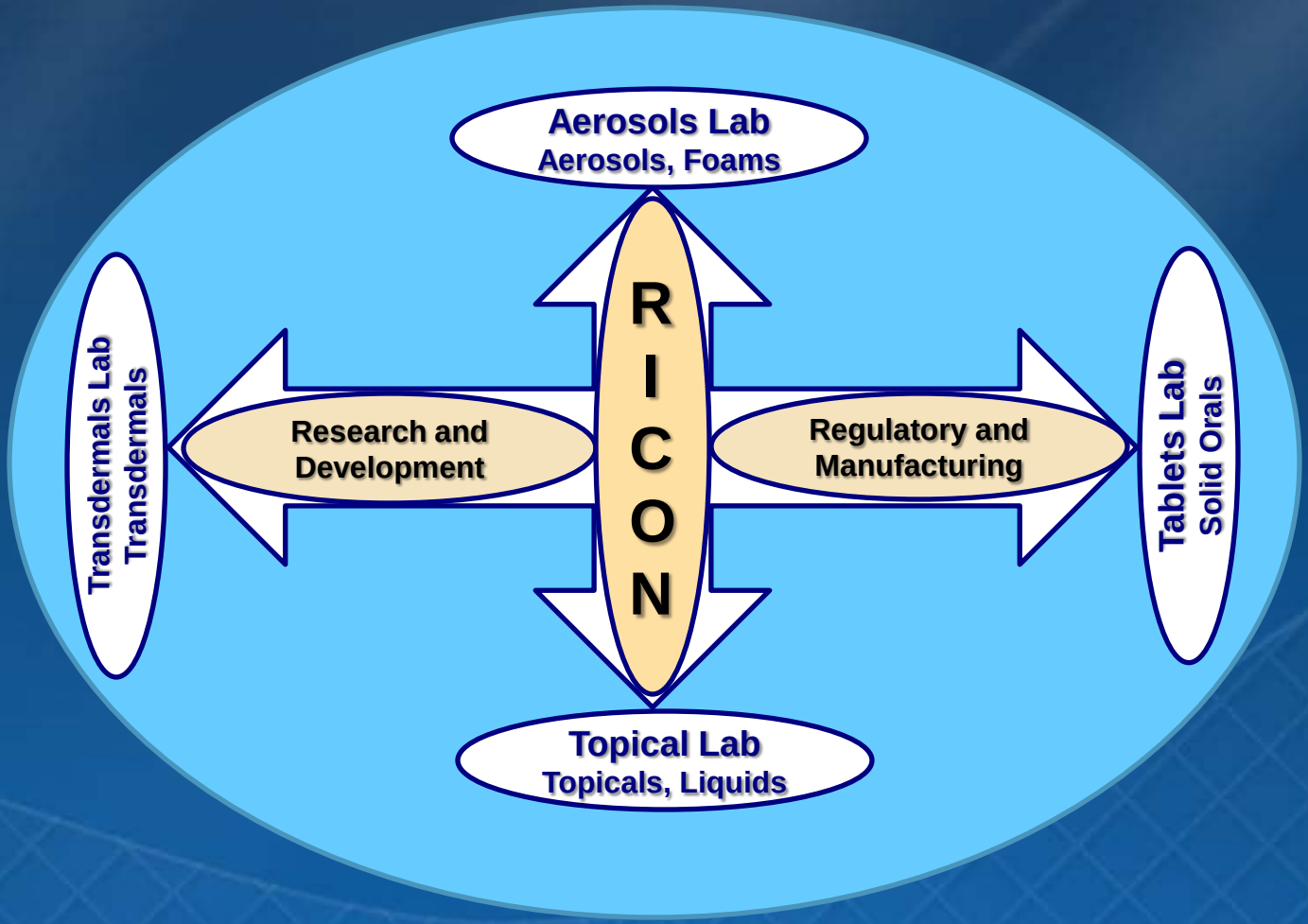
Dr. Satya Valiveti, VP, Preformulation and Analytical R & D
Satya has a Ph.D in Pharmaceutical Sciences with 10 years of proven hands on experience in pre-clinical formulations, pre-formulations, and formulation of Solid Orals, Topicals, and Transdermals in companies such as Pfizer and BI. He was also a Post-Doctoral Research Fellow at the University of Kentucky doing research on Transdermal and Topical drug delivery systems. He published over 90 publications and presentations in various peer reviewed journals, conferences and he is a reviewer for several journals

Dr. Praveen Reddy Billa, Managing Director, RiconPharma India Private Limited
Praveen has a Ph.D in Pharmaceutics with 16 + years of proven experience in Pre-formulations, Analytical R & D, Formulation Development, and Regulatory Submissions. He held key positions in Pharmaceutical R & D at Wockhardt, Dr. Reddy's and Orchid. He was instrumental in developing several ANDA's and challenged several Paragraph IV's. He has significant experience in Solid Oral Dosages, Topicals, Liquids, and Parenterals. He has several patents (US and WO) and publications.

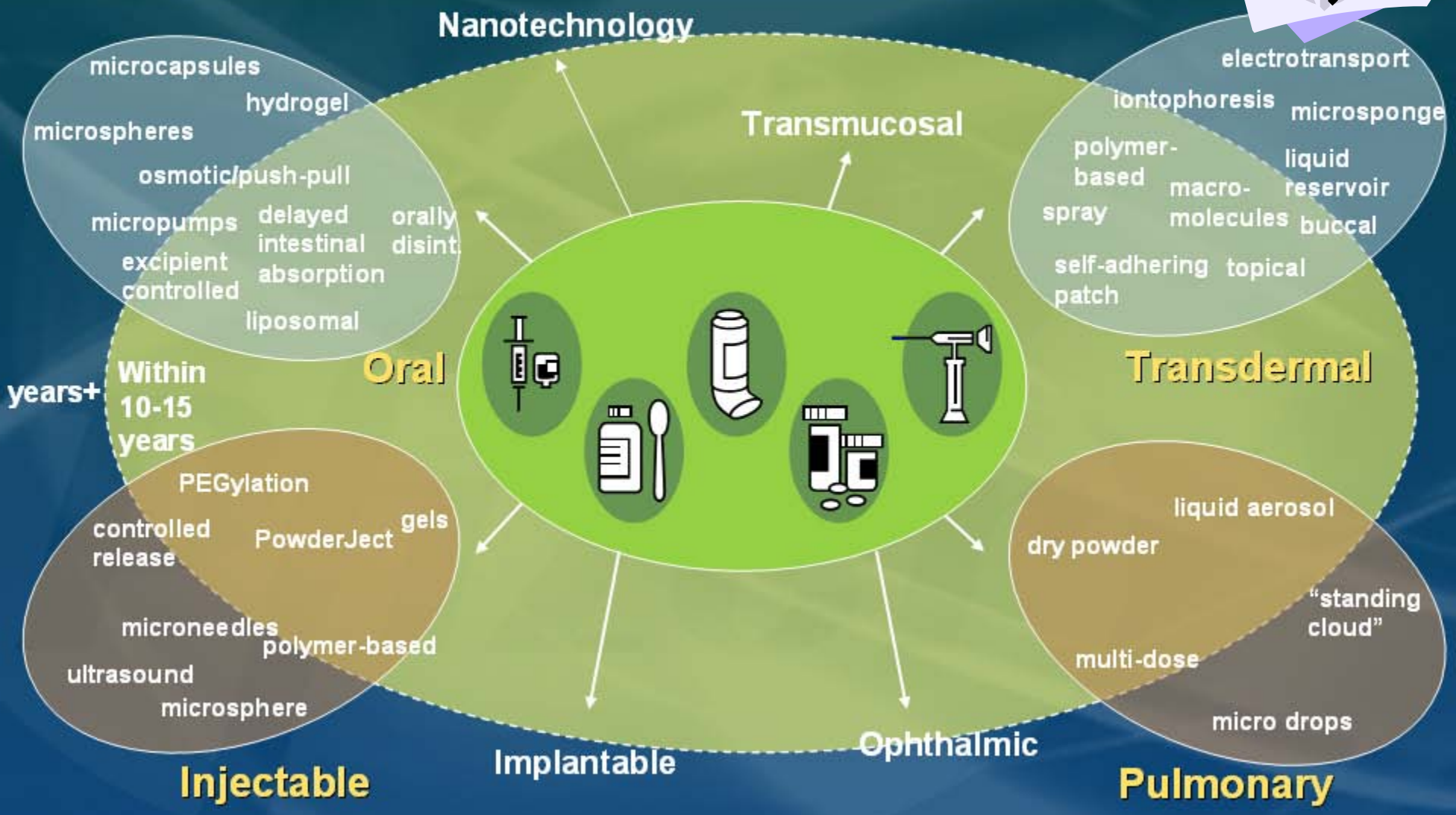
Mission Statement

Research Innovative Concepts in Pharmaceutical Development of Products and Processes using Advanced Manufacturing Technologies and Quality by Design (QbD) Principles for the 21st century

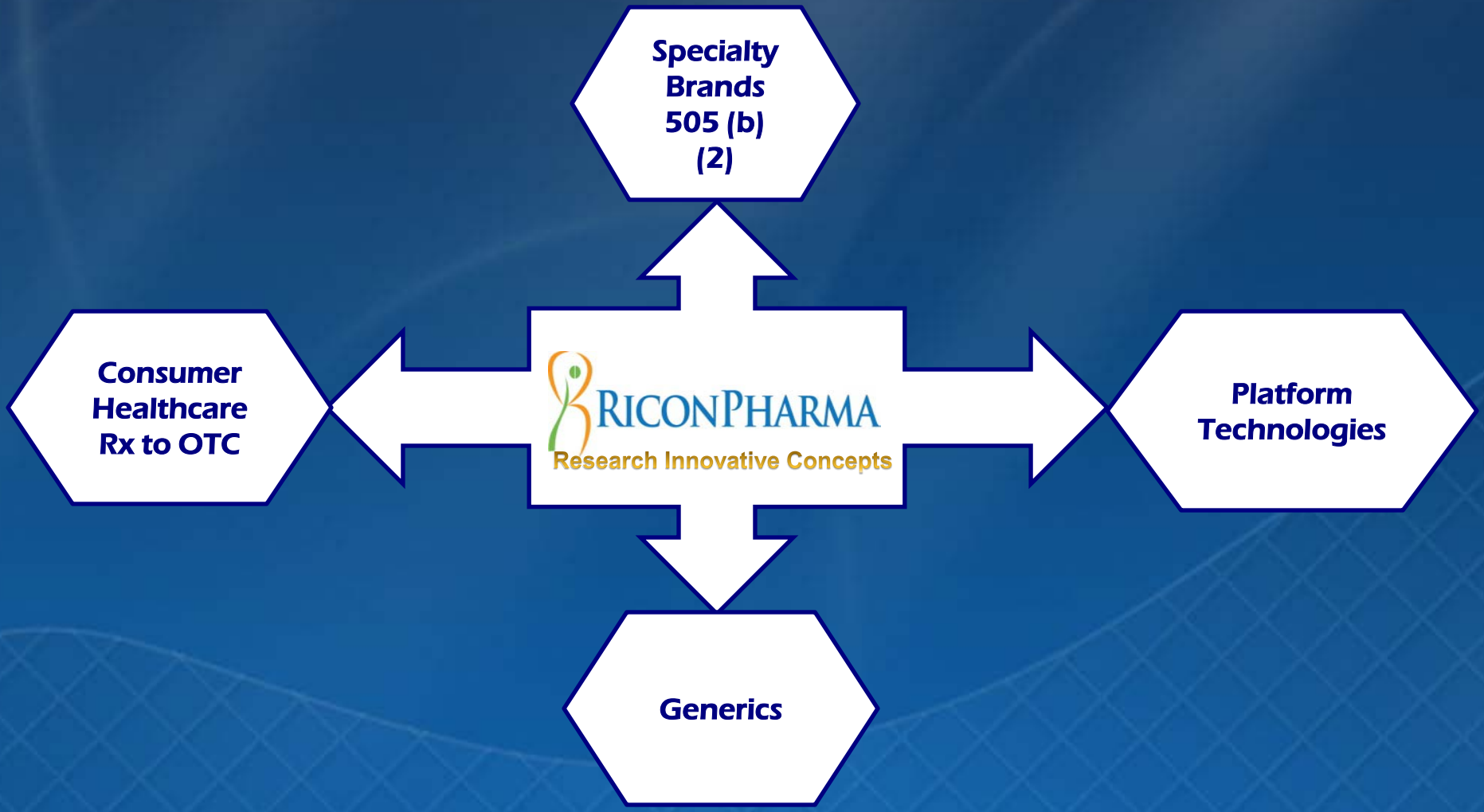
Our Vision
Pharmaceutical Center of Excellence - Strategic Linkages



An Explosion of New Drug Delivery Technologies



RiconPharma Key Business Areas



RiconPharma's Key Focus Areas

Value Chain Elements

Pre-formulation/ Analytical Development

- Polymorphic Screening
- Polymorph Stabilization
- Salt Screening
- RM compatibility Studies
- Material Characterization
- Solid State Characterization
- Diffusion Studies
- Method Development
- Method Validation
- Troubleshooting
- Stability Studies

Formulation Development

- Brand Drugs Specialty Drugs
- Combination Drugs
- Life-Cycle Mgmt.
- Product Enhancement
- Reformulations

Dosage Forms

1. Solid Orals
2. **Transdermals**
3. Topicals
4. Liquids
5. Injectables

Platform Technologies

- Abuse Deterrent
- Modified Release
- ODT
- Targeted Release
- Buccal Delivery

Manufacturing Development

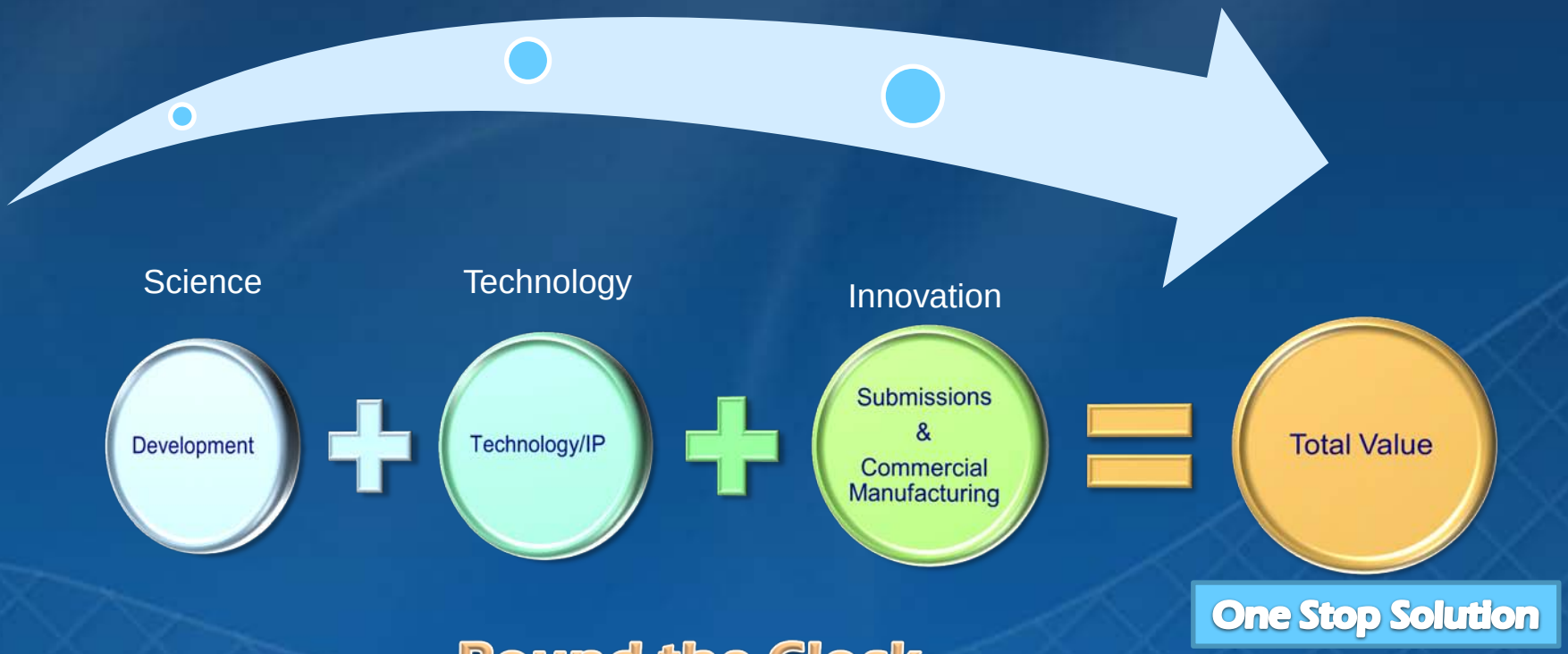
- Lead-time reduction
- Step-change productivity improvement
- Continuous Process/CQV
- Alternate Processing
- Automation
- PAT – RTR
- Process Control
- Process Modeling
- Process Mapping

Regulatory Affairs

- Pre-IND / IND
- Pre-NDA / NDA
- BA/BE/Clinical Studies
- Bridging Studies
- ANDA and NDA 505 (b) (2) Submissions
- Suitability Petitions
- Paragraph IV

Value Proposition

Cost Effective Development and Manufacturing



Round the Clock

RiconPharma's Business Model

Over the next 3 years due to patent loss the Brand Companies will lose $60 Billions in sales

About 28% revenues will be lost in during 2010 and 2011 by Big Pharma

Paradigm Shift

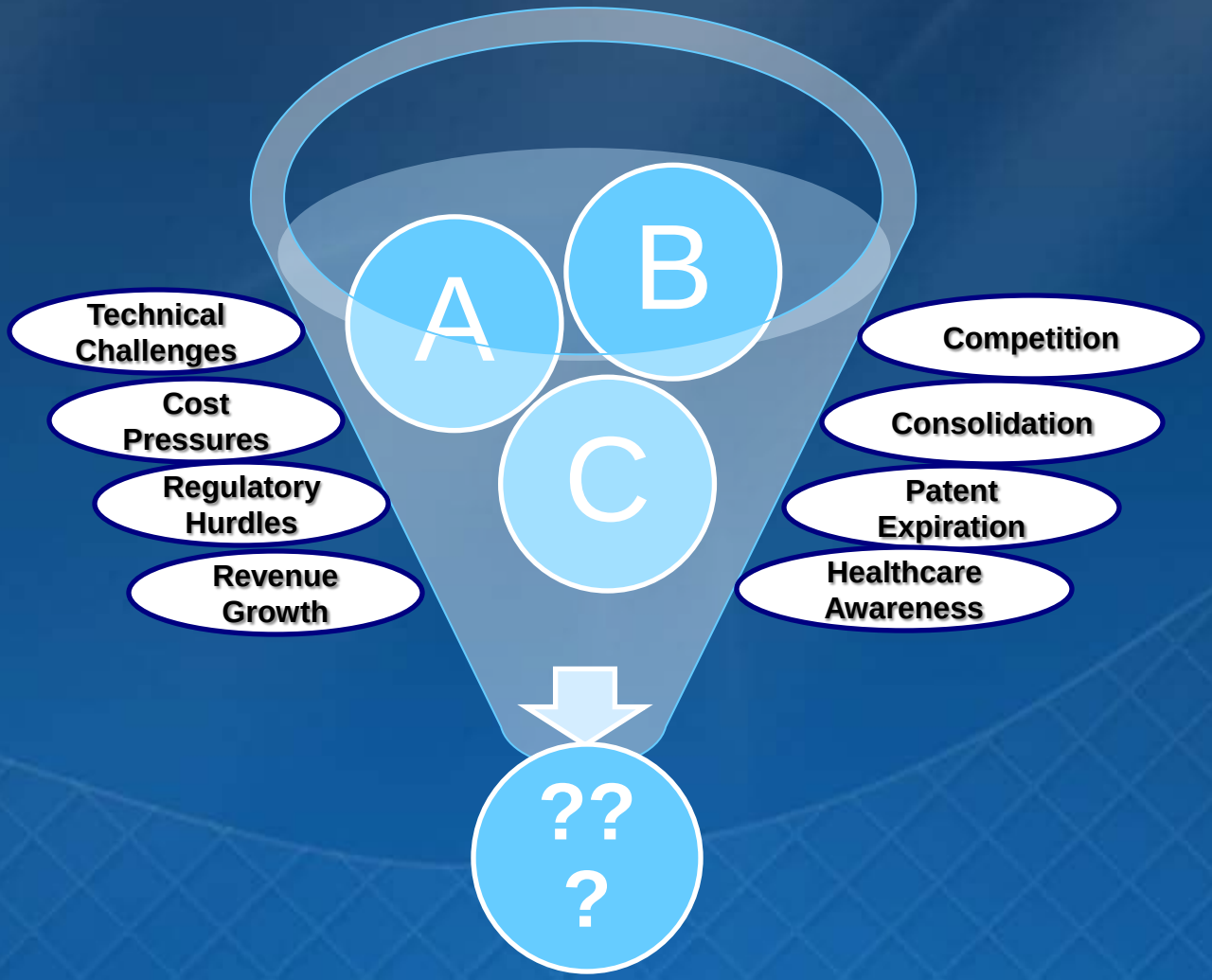
Classic Product Enhancement Example

Science, Innovation, and Technology

Features	Iphone 3 G	Iphone 3G S
Price	$99	$199 - $299
Storage	8 GB	16 GB – 32 GB
New Features	NA NA NA NA	Improved Performance Built-in Video Camera Voice Control Compass
Color	Black	Black & Silver
Battery Life	Internet Use 6 hours	Internet Use 9 hours
Camera	2 megapixels	3 megapixels Auto focus Video recording

Improved Performance with Additional Features for Consumer Benefit

Product Enhancement and Life Cycle Management
Key Business Drivers

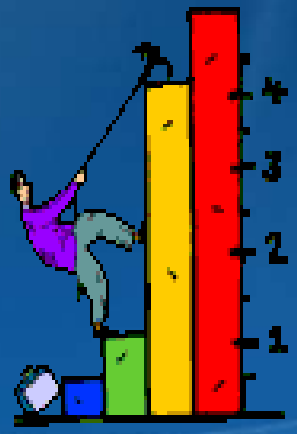


Product Enhancement Opportunities (NDA 505 (b) (2) filing)

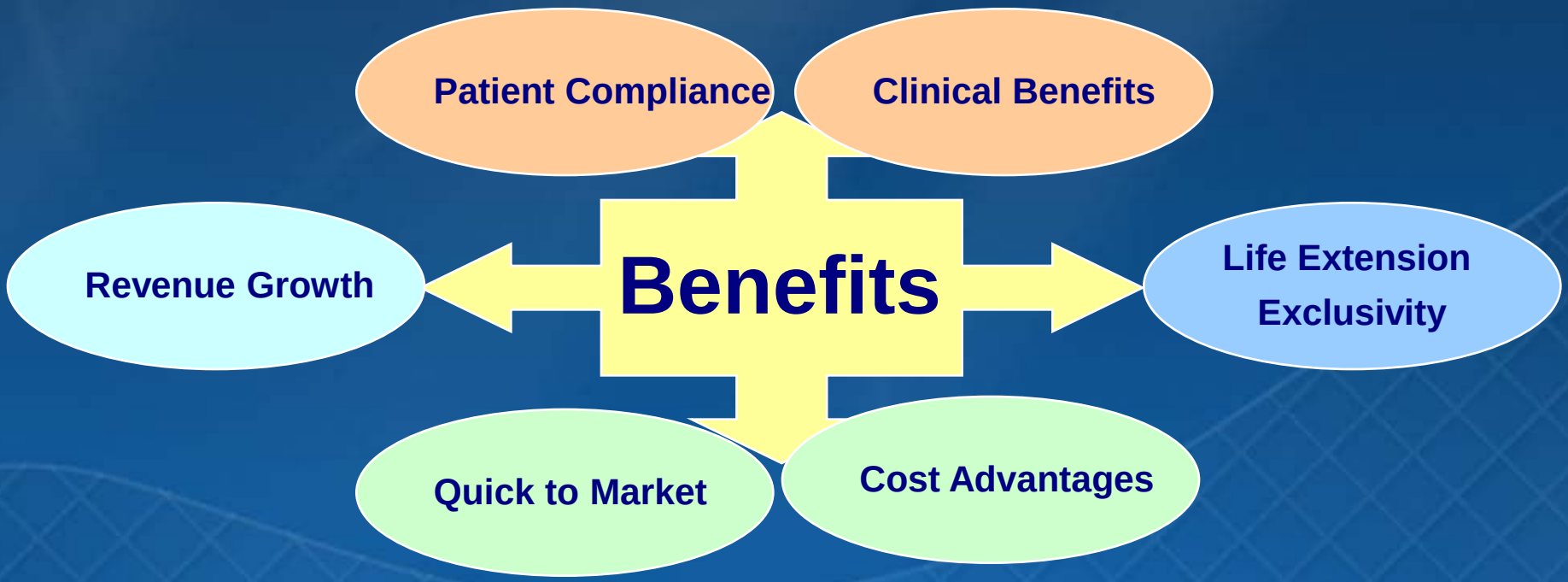
- **Dosage Form Variations**
  - ✓Immediate Release to Modified Release, Orally Disintegrating, and Buccal Tablets
  - ✓Combination Therapy (Single active to two actives or substitution of an active in a combination product)
  - ✓Tablets to Transdermals
  - ✓Creams to Gels to Foams
- **Bio-availability Enhancements, Clinical Variations and Therapeutic Changes**
  - ✓Dosage Strength Reductions
  - ✓Side Effects Reductions
- **Bio-availability Slow-down**
  - ✓Dosage Frequency Reductions (Multiple dosing to Once a day dosing)
  - ✓Delayed Release and Targeted Release
- **Route of administration**
  - ✓IV to intrathecal
- **New Indications**
- **Substitution of and active ingredient in a combination product**

Product Enhancement Challenges

1. Product and Process Understanding
2. Science and Technology Challenges
3. Safety and Efficacy Challenges (Bridging Clinical and Bio-Studies)
4. Regulatory Challenges (Rationale and Justification for FDA buy in)
5. Barrier to entry (Patents and IP)
6. Cost of Development and Manufacturing
7. Patents and IP Challenges
8. Competition
9. Marketing and Detailing
10. Time to market

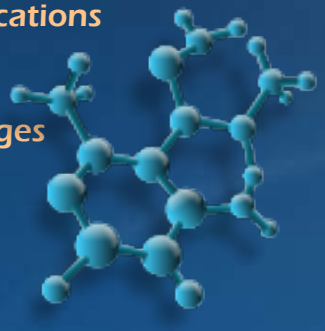


Product Enhancement and Life Cycle Management Benefits



Product Enhancement Approaches

- API modifications
  - ✓Molecular Modifications
  - ✓Salt Changes
  - ✓Polymorph Changes
  - ✓Co-Crystals
  - ✓Nano-Crystals
  - ✓Co-Precipitations
  - ✓Co-Processing
  - ✓Co-Micronization



- Drug Product Changes
  - ✓Combination Drugs
  - ✓Dosage Form Changes
  - ✓Formulation Changes
  - ✓Excipient Changes

Product Enhancement Approaches

- **Technology Platforms**
  - ✓Modified Release Technologies
  - ✓Targeted Release Technologies
  - ✓Nano-Technologies
  - ✓Spray Dispersion Technologies
  - ✓Melt Extrusion Technologies
  - ✓Abuse Deterrent Technologies

- **Other Approaches for enhancing the profits and sustain the markets**
  - ✓Process Enhancements such as alternate processes, continuous processes, process analytical technologies
  - ✓Sourcing Strategies
  - ✓Cycle Time reductions and Capacity enhancements
  - ✓Manufacturing site changes (Low Cost Locations)

RiconPharma's Product Development Pathway

Proof of Concept

- Product Identification and Product Enhancement Planning
- Pre-IND Meeting, Product Development Planning
- Pre-formulation, Analytical Methods Development, Formulation Feasibility Studies
- Pilot Scale Clinical Studies

Manufacturing Development

- Process Development
- Scale-up, and Technology Transfer
- Pivotal Clinical Studies
- ICH Stability Studies

Commercial Development

- Regulatory Submissions
  NDA 505 (b) (2)
- Launch Planning
- Validations and PAI
- Commercial Supply and Continuous Improvement

PARTNERSHIP

Accomplishments Since Formation

1. Established state of the art R & D Labs in the US and India to support at least 30 projects in a year.

2. Successfully completed two pre-IND meetings with FDA.

3. Established Collaborative Product Development and Joint Venture Agreements with four Pharmaceutical Companies.

4. Established Collaborative Agreements with four manufacturing companies to manufacture the products that we develop.

5. Presently working on several active projects of which we have marketing partners.

6. Signed a Master Service Agreement with a major Pharmaceutical Company to provide Pre-formulation, Formulation, and Analytical Support.

Formulation and Processing Technologies

RiconPharma has the following formulation and processing capabilities:

- **Solid Orals (Immediate Release and Extended Release)**
  1. **Direct Compression**
  2. **Dry Granulation**
  3. **Wet Granulation and Drying (High-shear Fluid Bed Drying)**
  4. **Fluid Bed Granulation and Drying**
  5. **Hot Melt Extrusion**
  6. **Wurster Coating**

- **Topicals (Immediate and Extended Release)**
  1. **Ointments and Creams**
  2. **Solutions and Lotions**
  3. **Foams and Gels**

- **Transdermal Patches**
  1. **Matrix**
  2. **Reservoir**

- **Liquids**
  1. **Solutions**
  2. **Syrups**
  3. **Suspensions**
  4. **Sprays**

Facilities, Resources, and Infrastructure

- 10,000 sq.ft., state of the art facility in Denville, NJ, USA
  - Capabilities for Solid Orals, Topicals, Transdermals, and Liquid Formulations
  - Capabilities to handle Schedule drugs (II-V) under DEA Research License
  - Capabilities to handle potent compounds for development
  - State of art Pre-formulations, Materials Characterization, and Analytical Methods Development
  - State of the art Diffusion Labs to conduct skin permeation and diffusion studies
  - Pilot Scale cGMP Manufacturing Capabilities
  - Expertise in Paragraph IV Challenges
  - ANDA and NDA 505 (b) (2) submissions capabilities
  - Recruited 25 talented scientists (4 PH.D's, 18 MS, 2 BS, 2 Associate degrees)

- 6,000 sq.ft., state of the art facility in Kukatpally, Hyderabad, India
  - Capabilities for Solid Orals. Expanding into Liquid, and Parenteral Formulations
  - State of art Pre-formulations, Materials Characterization, and Analytical Methods Development
  - Expertise in Paragraph IV Challenges
  - ANDA and NDA 505 (b) (2) submissions capabilities
  - Recruited 5 talented scientists (1 PH.D and 4 MS)

Equipment and Instrument List

Equipment:

- Silverson Mixer
- Homogenizer
- HSM Bench top Emulsifier/High Sheer Mixer
- Manual Coater and Patch Maker
- High-shear Granulator (5 L and 25 L)
- Roller Compactor
- Glove Box
- Blenders (PK and Bin)
- Tablet Press (10 Station)
- Fluid Bed Processor
- Tablet Coater
- Comil and Fitzmill
- Single Punch Tablet Machine
- Friability Tester
- Hardness Tester
- Density Tester
- ATM Sonic Sifter
- Over Drier
- Freeze Dryer
- Isolators for containment products
- Master Flex Pumps
- Induction Sealer

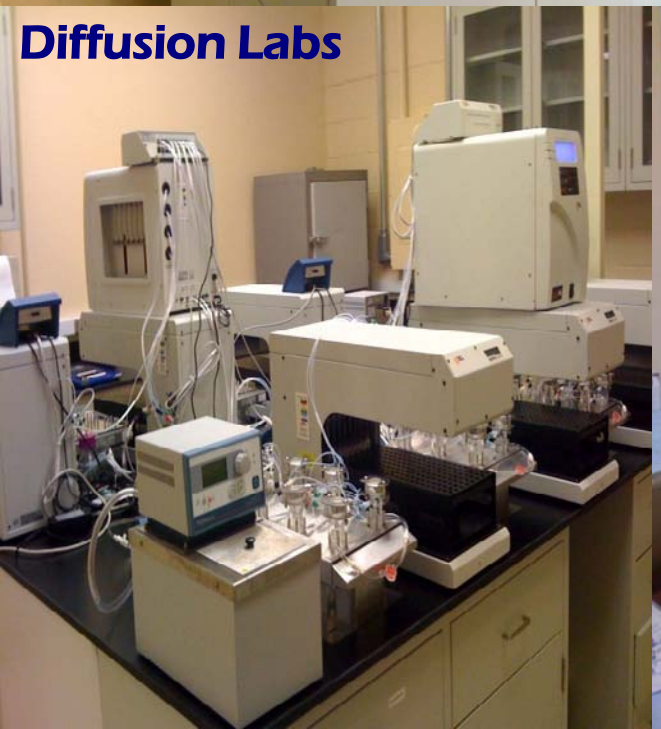
Analytical Instruments

HPLC (8)
Dissolution Testing Apparatus (8)
Bio-dissolution Tester (1)
XRD (Powder X-Ray Diffraction)
FTIR
ELSD
Nikon SPPI Microscope for pictures of particles
DSC
TGA
DVS (Dynamic Vapor Sorption)
Particle Size (Malvern Mastersizer and Zetasizer)
Hanson Research Diffusion Set-up
Manual Diffusion Set-up
LC/MS/MS
FOSS NIR Rapid Content Analyzer
Spectralliance NIR (PAT)
UV Spectroscopy
PH Meters
Carl Fisher Set-up
GC
Moisture Balance
Viscometer


Formulation Labs


Process Labs


Process Labs


Diffusion Labs


XRD Labs


Analytical Labs

Manufacturing Technology Expertise

Process /Technology Development Skills:

- Develop Innovative Processing Technologies
  - -Semi-Continuous
  - -Continuous Processing
- Design Space and Process Understanding
  - -DOE, LVM, Statistical Analysis
- Process Robustness and Capability
  - -Six Sigma, DMAIC
- Automation, PAT, and Advanced Process Controls
  - -Continuous Quality Verification
  - -Feed Forward and Feed Backward Control Loop
  - -Parametric and Real Time Release
- Patents and Intellectual Properties

Equipment/Process Capabilities

High-shear Granulation, Fluid Bed Granulation/Drying, Particle Coating, Blending, Milling, Tableting, Coating, and Lyophilization

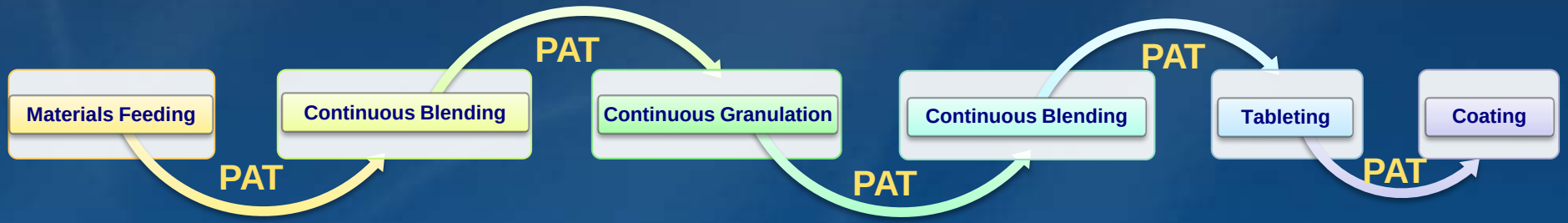
Continuous Pharmaceutical Manufacturing

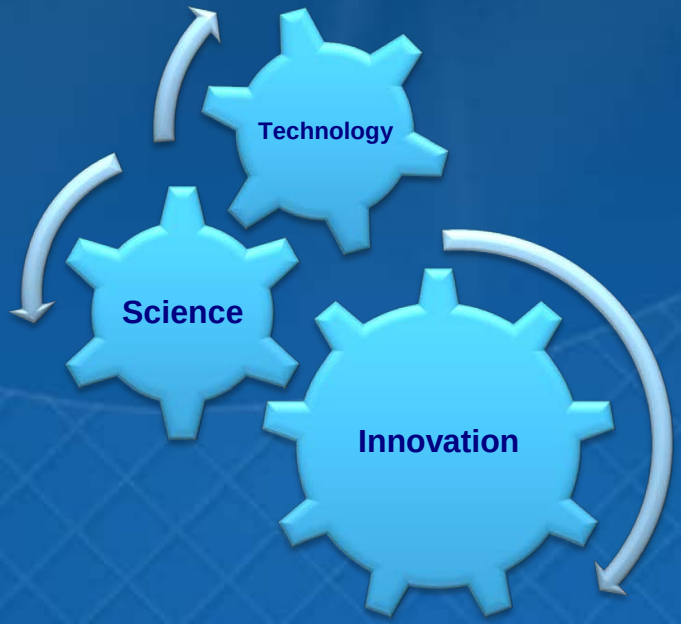
- Continuous manufacturing processes and other innovative technologies are expected to be incorporated in pharmaceutical manufacturing to *improve quality* and *lower the cost of pharmaceuticals*

- The recent $65 million agreement signed between Novartis and MIT aimed at the development of continuous processing is a good example.

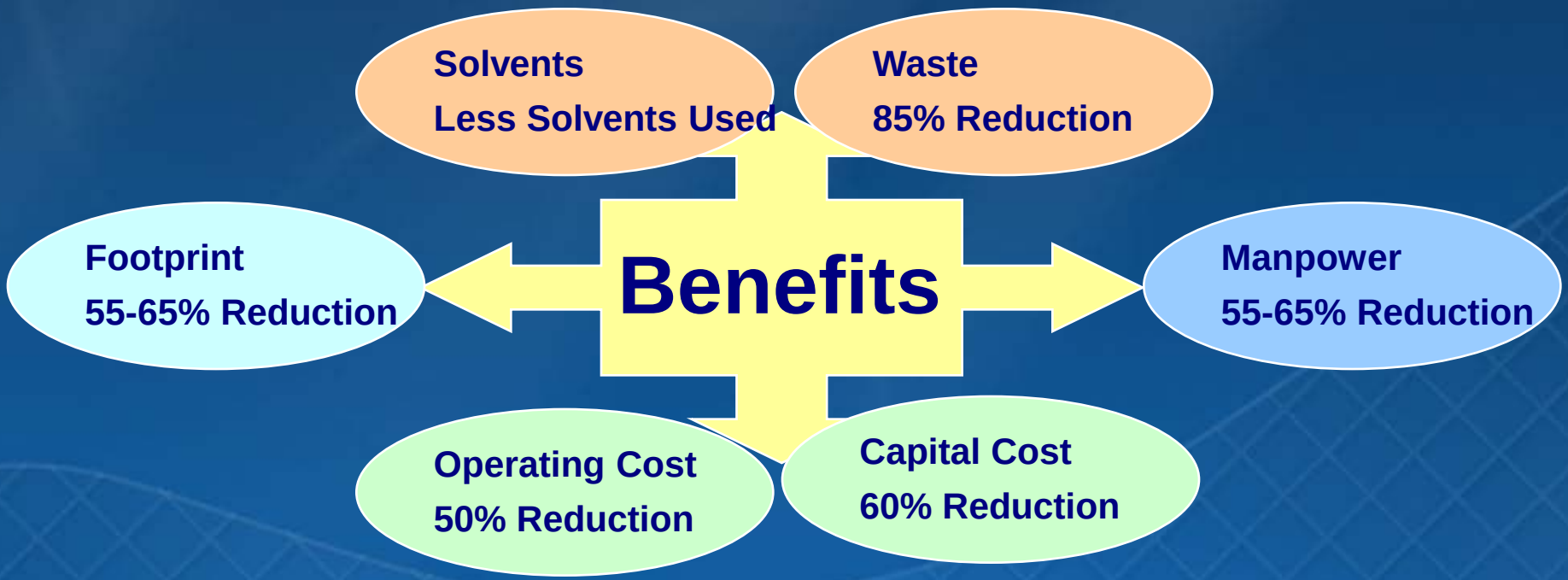
- The funding and promoting of research on continuous processing technologies by the National Institute of Pharmaceutical Technology and Education (NIPTE) is another

Continuous Manufacturing through Continuous Quality Verification





Continuous Processing-Benefits



O'Neal's Advanced Technology Research Group

What RiconPharma can do for the partner?

1. Enhance Partner's R & D output by developing a basket of value added products (ANDA and NDA 505 (b) (2)) such as Transdermals, Solid Orals, Inhalers, Topicals, and Liquids. (Strategic Development Partner)

2. Develop and file 10 -15 good products every year to increase the value in the next 5 years.

3. Provide Formulation, Analytical, Technical, and Regulatory Management support.