



Mikart 

We Bring Your Product To Life™

Mikart Campus



Seven Buildings

Primary Business Areas

- ▶ Formulation Development
- ▶ Regulatory Submission Services
- ▶ Manufacturing
 - Clinical Trial Materials
 - Commercial Products
- ▶ Packaging
 - Clinical Supplies
 - Physician Samples
 - Trade Packs



Process Development

- ▶ Direct Compression
- ▶ Dry Granulation
 - Roller Compaction
 - Slugging
- ▶ Wet Granulation
 - High Shear
 - Low Shear
- ▶ Low Humidity Manufacturing
- ▶ Fluid Bed Granulation
 - Top Spray
 - Wurster
- ▶ Coating
 - Fluid Bed Coating
 - Tablet Coating



Analytical Development Services

- ▶ Pre-Formulation Research & Testing
- ▶ Cleaning Verification & Validation
- ▶ API Characterization
- ▶ API & Finished Product Development, Validation and Transfer of Stability Indicating Methods
- ▶ Methods (TOC, HPLC, UPLC, UV, GC)
 - Dissolution Testing (IR, XR, MR)
 - AA (Atomic Absorption)
 - Water Activity



QC and Micro Laboratories

- ▶ Raw Material Testing
- ▶ Stability Testing
- ▶ Compendial Testing (USP, EP, BP, JP, FCC)
- ▶ Finished Product Testing
- ▶ Water and Raw Material Testing
- ▶ Finished Product and Stability Microbial Analysis
- ▶ Environmental Monitoring



Manufacturing

- ▶ Exhibit Batches
- ▶ Clinical Trial Supplies
- ▶ Commercial Product



Manufacturing

▶ Tablets & Capsules

- Immediate & Controlled (Modified) Release
- Film Coating
- Fast Dissolve (ODT)
- Chewable Tablets
- Sublingual Tablets
- Low Humidity Manufacturing

▶ Powders in bottles

▶ Non-Sterile Liquids

- Oral Solutions
- Unit dose solutions



Industry Standard Equipment



- ▶ Fluid Bed Granulation
- ▶ Fluid Bed Drying



Industry Standard Equipment

- ▶ High Shear Granulating



Industry Standard Equipment

- ▶ Tableting



Industry Standard Equipment

- ▶ Encapsulating



Industry Standard Equipment

- ▶ Blister Packaging / Cartoning



Industry Standard Equipment

- ▶ Roller Compacting



Serialization

- ▶ 2023 DSCSA Compliant Packaging
 - Bottles
 - Cartons
 - Tray Pack Bundles
 - Shippers
 - Pallets



Track & Trace



Unit
Level



Bundle



Shipper Case



Pallet Aggregation

Packaging

- ▶ Bottles (15cc - 1250cc)
 - HDPE
 - PET
 - Glass



Packaging

- ▶ Unit Dose
 - Blisters (Thermo & Cold-Formed)
 - Laminated Foil Pouches



Packaging

- ▶ Unit Dose
 - Single Use Liquid Cups
 - Bottle Powder Filing

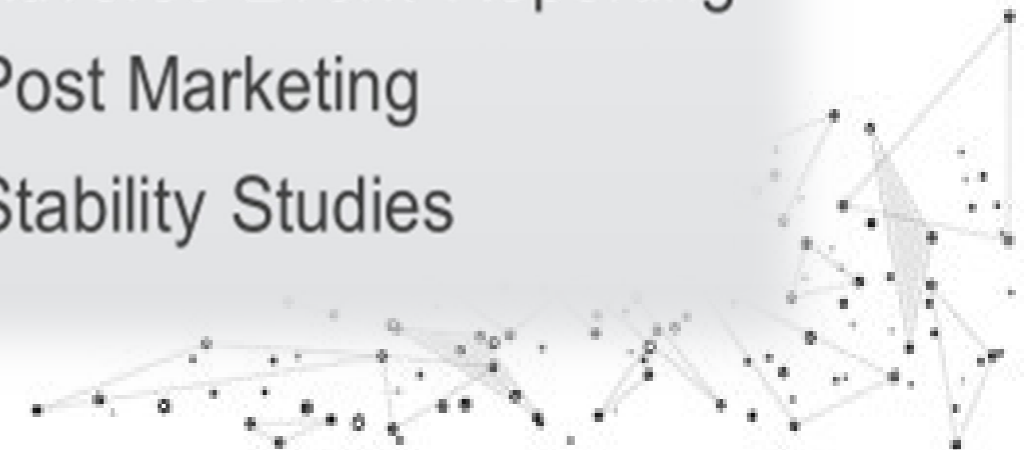


► Pre-Approval

- Original Applications
IND/NDA/ ANDA (in eCTD format)
- QOS (Quality Overall Summary)
- SPL (Structured Product Labeling)
 - Amendments to Existing Applications
 - Petitions
 - Label/Outsert Design

► Post-Approval

- Supplements
 - Prior-approval
 - CBE-0
 - CBE-30
- Label Revision
- File maintenance including Annual Reports
- Adverse Event Reporting
- Post Marketing Stability Studies



Project Management



- ▶ Your advocate within Mikart
- ▶ Develop Project Timelines
- ▶ Delivers the plan by managing the Mikart team
- ▶ Agrees the right type of customized communication with you as a client
- ▶ Timely Status Reporting and Conference Calls to update progress
- ▶ Weekly Internal Project Meetings



Quality Control/Analytical Lab

❖ Instrument Availability

➤ HPLCs:

- 33 *Waters* (Alliances & Modular w/UV and PDA detectors)
- 4 *Agilent* (1100 & 1200)

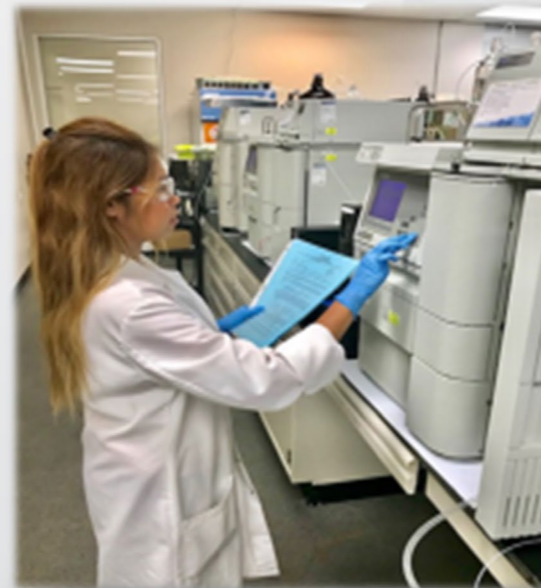


➤ UPLCs:

- 5 *Waters* (Acquity)

➤ Hybrid HPLC/UPLCs:

- 1 *Waters* (Acquity H-class)
- 1 *Agilent* (1290)



Quality Control/Analytical Lab

➤ FTIR

- *Perkin Elmer Spectrum One w UATR accessory*

➤ Particle Size Analyzers:

- *Micron Air Jet Sieve*
- *Fritsch Vibrational Shaker*
- *Rotap Tap Density Shaker*
- *Malvern Laser Diffraction Particle Size Analyzer (outsource)*



➤ GCs:

- *5 Agilent (6890 & 7890)*

➤ Viscometers

- *Brookfield LVT Viscometer*
- *Brookfield DV2T Viscometer*



Quality Control/Analytical Lab

- **UV/Vis Spectrophotometers:**
 - *Perkin Elmer Lambda 35*
 - *Agilent Cary 100*
 - *Agilent 8453*
- **Atomic Absorption Spectrophotometer**
 - *AAAnalyst 400 w/autosampler*
- **Polarimeter**
 - *Rudolph Research Autopol IV*
- **Refractometer**
 - *Rudolph Research J457*
- **Dissolution Testers**
 - *Teledyne Hanson (4 Vision & 8 SR8+)*



Quality Control/Analytical Lab

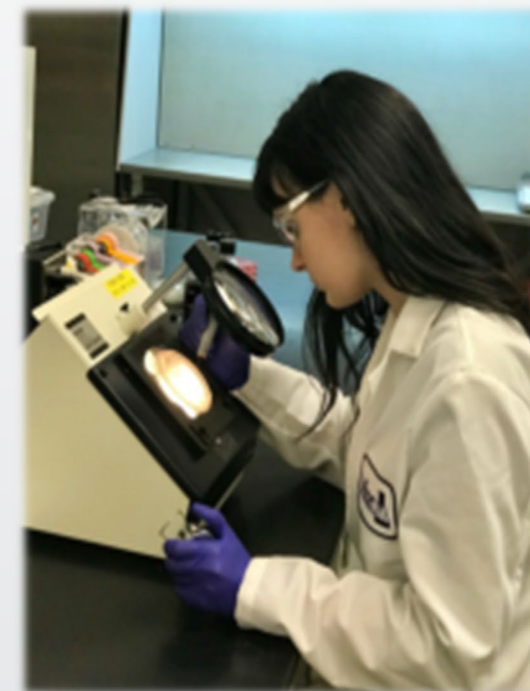
❖ Analytical Lab Documentation

- Carbon Copy Sequentially Numbered Bound Laboratory Notebooks
- Daily Verification Balance & pH Logbooks
- Sample Receipt Logbooks (raw materials, finished products, stability)
- Instrument Usage Logbooks
- InvMan Database (inventory of all reagents and lab supplies)
- House Standard Logbooks
- Controlled Substance Logbooks
- Test Solutions Logbooks
- *LMS coming 2021*



Microbial Assay <81>

- ▶ Method Verification of Antibiotic microbial assay <81>



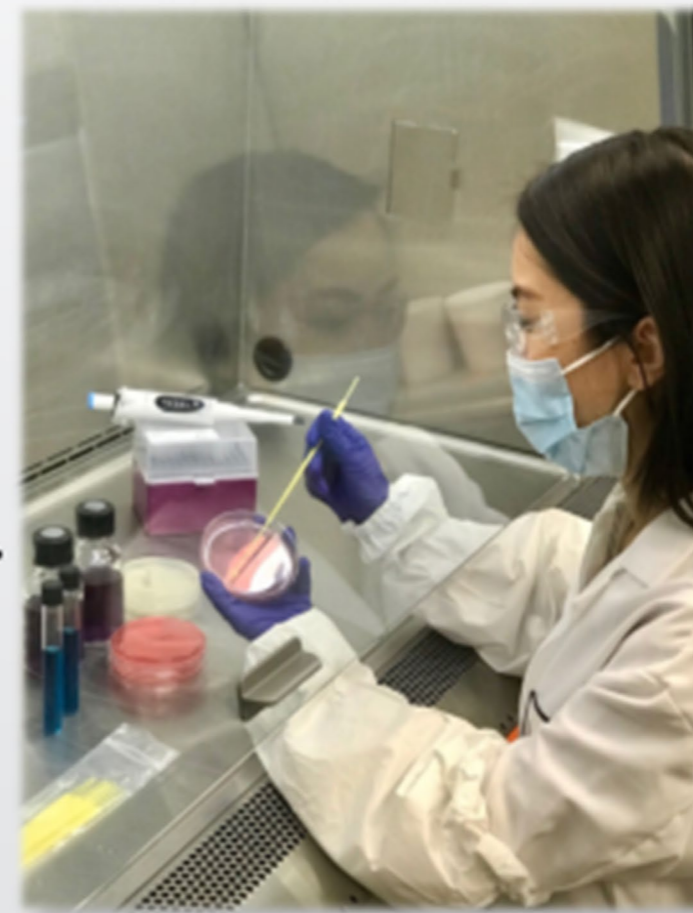
Microbial Assay <81>

- ▶ Method Verification of Antibiotic microbial assay <81>
 - Resources available on site:
 - Qualified and calibrated incubators
 - Asset #2485, #2118 (30.0-35.0 °C)
 - Asset #2119 (34.0-36.0 °C)
 - Digital Caliper #2554 sensitive to 0.01mm
 - Test organism – Bacillus Subtilis ATCC 6633
- ▶ 5-7 days required for testing Microbial assay <81> of product development batches



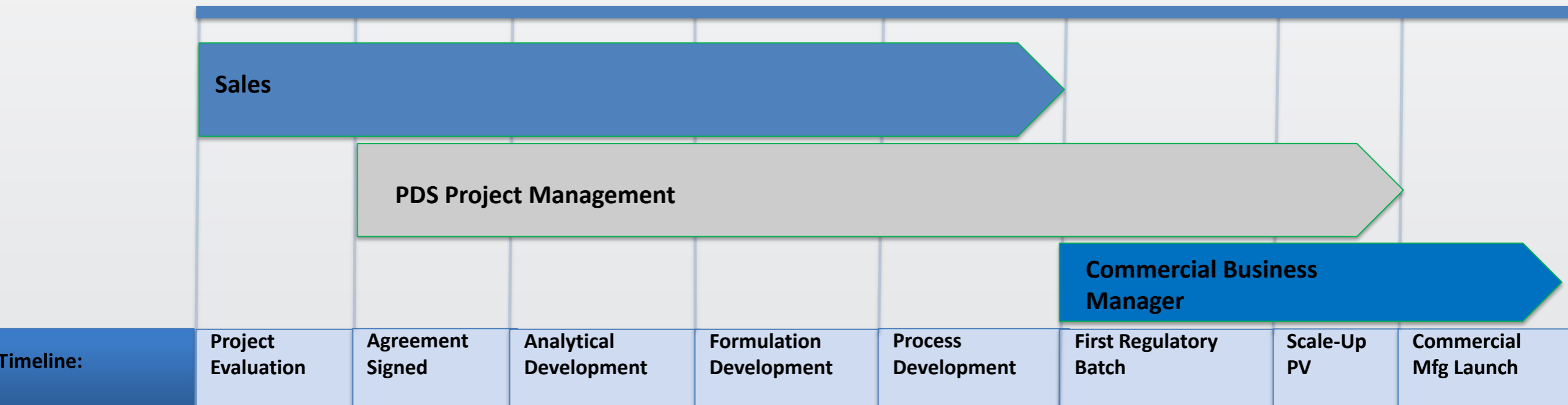
Microbial Limits <61> and <62>

- ▶ Suitability testing (pending receipt of API and excipients)
 - Effectively neutralize antibiotic
 - 2-4 weeks
- ▶ Product Development batches
 - Total Aerobic Microbial Count <61>
 - 3-5 Days
 - Total Combined Yeast and Mold Count <61>
 - 5-7 Days
 - Specified Microorganisms <62>
 - ▶ 2-4 Days



Project Execution

- CDMO built to service both development & commercial customers
- Sales focused on business relationship
- Project Management focused on successful development & tech transfers
- Smooth transfer from development phase to commercial
- Commercial Business Manager/Supply Chain focused on commercial supply



Overlap of responsibilities ensures successful handoffs & execution