

# American Association of Pharmaceutical Scientists (AAPS)

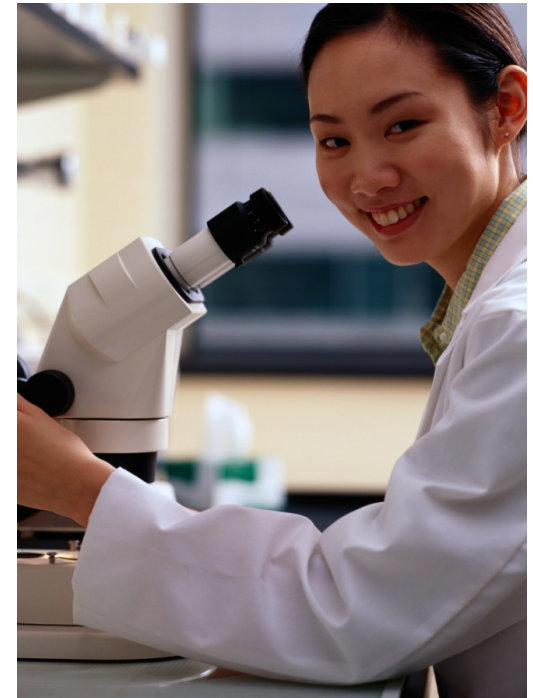
- AAPS is a professional, scientific association of approximately 11,000 pharmaceutical scientists employed in industry, academia, government, and other research institutes worldwide.
- AAPS provides a dynamic international forum for the exchange of knowledge among scientists to enhance their contributions to health.
- We offer timely scientific programs, ongoing education, opportunities for networking, and professional development.
- AAPS is the premier organization of all scientists dedicated to the discovery and development of products and therapies through advances in science and technology.

***<https://www.AAPS.org>***

# Student and Faculty Benefits

## AAPS Coordinates:

- Visiting Scientists and Industry Tours
  - Provides colleges and faculty w/ access to expert industry scientists and insight into careers in BioPharma
- Mentoring Events
- Networking and Professional Development
- Student Chapters
- Awards and Travelships
- Student-initiated Program Funding
- Student Reps to Sections and Committees
- Complimentary Memberships
- K-12 outreach
- eLearning Courses and Monthly Webinars
- Annual meetings
- Online Career Center



# Student Post-Doc Outreach Development (SPOD)

## More than 2,000 student and postdoc members

- 96 student chapters in 18 countries
- \$10,000 in section visiting scientist funding
- \$50,000 in grants and fellowships
- \$60,000 provided annually for student-initiated programs
- \$90,000 in stipends currently budgeted for students

## eLearning Courses

- Biotech 101
- Regulatory affairs 101
- Immunogenicity 101
- TransSci 101
- More to come...



# Sections within AAPS

- APQ - Analysis and Pharmaceutical Quality section
- **BIOTEC - Biotechnology section**
- CPTR - Clinical Pharmacology and Translational Research section
- DDDI - Drug Discovery and Development Interface section
- FDD - Formulation Design and Development section
- MSE - Manufacturing Science and Engineering section
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- RS - Regulatory Sciences section

# LBABFG within AAPS

**BIOTEC Section**  
Chair: Meena Subramanyam (Biogen Idec)

**Ligand Binding Assay Bioanalytical Focus Group**  
Chair: Lindsay King (Pfizer)  
Chair Elect: Heather Myler (BMS)

**PK DG**  
Lead: Mark Ma & Boris Gorovits

**Immunogenicity DG**  
Leads: Shalini Gupta & Yuanxin Xu

**Biomarker DG**  
Sponsor: Lakshmi Amaravadi & Steve Eck

**LBA Technologies DG**  
Leads: Fabio Garofolo & Stephanie Fraser

**Communications and Education DG**  
Leads: Sue Spitz & Joe Marini

Protein Aggregation and Biological Consequences FG

Biosimilars FG

Therapeutic Product Immunogenicity FG

Bioanalytical FG

Generic Pharmaceuticals FG

Lipid-Based Drug Delivery Systems FG

Pharmaceuticals in Global Health FG

**Other Sections**

Pharmacogenomics FG

Preformulation FG

Biomarkers in Translational Medicine FG

Sterile Products FG

Systems Biology FG

DG = Discussion Group

# Focus Group Activities

- Publications to influence regulatory activities
- Production of e-Courses and Webinars
  - <https://www.aaps.org/eCourses/>
    - *Example:* AAPS Biotechnology 101
  - <https://www.aaps.org/webinars/>
    - **AAPS Webinars - Free and Exclusive to Members**
    - *Example:* Large Molecule PK Assay Development—The Principles and Practices
- Development of programming for national and local meetings



- **MIRA opens 17-Aug-2016 and closes 27-Oct-2016.**
- **2017 NBC Themes**
  - ❖ Novel Therapeutic Constructs
  - ❖ Bioanalysis and Biomarkers
  - ❖ Formulation Development and Drug Delivery
  - ❖ Immunotherapies
  - ❖ Biosimilars
- **Program Highlights**
  - ❖ Biotechnology Graduate Student Symposium
  - ❖ BioTalk: lunch and learn with networking opportunity
- **Professional Development**
  - ❖ Mentoring Breakfast
  - ❖ Resume Review
  - ❖ 2-4 Professional Development sessions



# Drug Development

Discovery

Pre-clinical

Clinical

Regulatory  
Review/  
Approval

Marketing and  
Life Cycle  
Mngmnt

**Discovery Research:** Biochemistry, *analytical*, pharmacology, protein engineering, ADME, toxicology, chemistry, informatics

**Development Research:** Biochemistry, *analytical*, pharmaceutical sciences, clinical trial management, statistics

**Manufacturing:** Engineering, biochemistry, *analytical*, operations

**Medical:** Clinical development, technical writing, regulatory, project management, pharmacovigilance, operations



# Pharmacokinetics

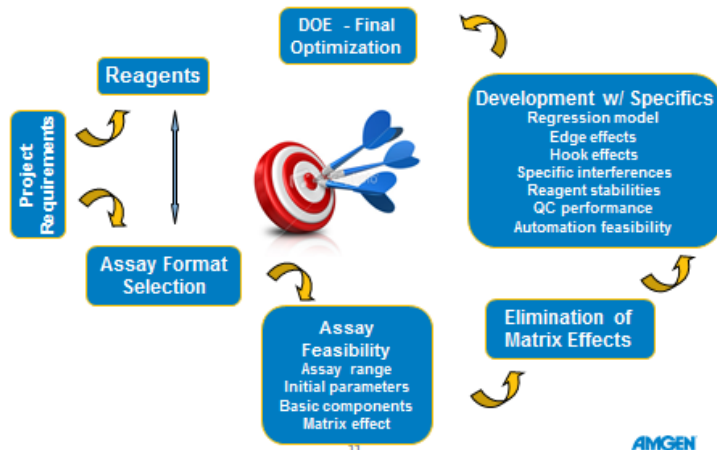
## PK assays enable us to understand what the body does to the drug

- Bioanalytical scientists establish strategies to develop, validate, and implement PK assays in support of novel therapeutics including: Mab, proteins/peptides, ADC, bispecifics, Bites, multi-functional drugs, vaccines and more...
- Utilize talents from across industry to understand the biophysical and pharmacological characteristics of a drug and customize the bioanalytical approaches accordingly
- Promote collaboration across industry
- Opportunity to influence regulatory agencies

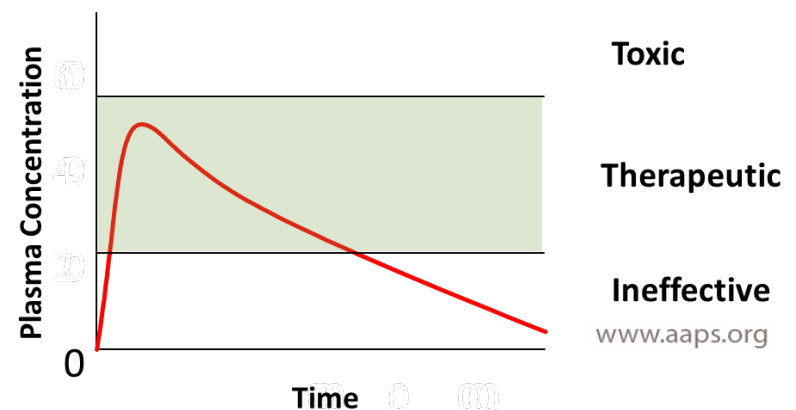
## Pharmacokinetics is very important in drug development:

- Assumption: the safety (adverse effects) and efficacy (therapeutic effects) of a drug are related to its concentration

### LM PK Method Development



### The Therapeutic Window



# Immunogenicity

- All biologics have the potential to elicit an immune response
- Clinical consequences can range from benign to life threatening
- Regulatory agencies recommend the adoption of a risk-based approach to evaluate and mitigate immune responses to therapeutics
- Immunogenicity testing is an important component of preclinical and clinical development of biologics

Injection Site Reactions/ Local hypersensitivity

Altered PK and Drug Exposure

Altered PD/efficacy and Drug Neutralization

Immune Complex Deposition -Serum Sickness

Endogenous Cross-reactivity

Anaphylaxis

Guidance for Industry  
Assay Development for  
Immunogenicity Testing of  
Therapeutic Proteins

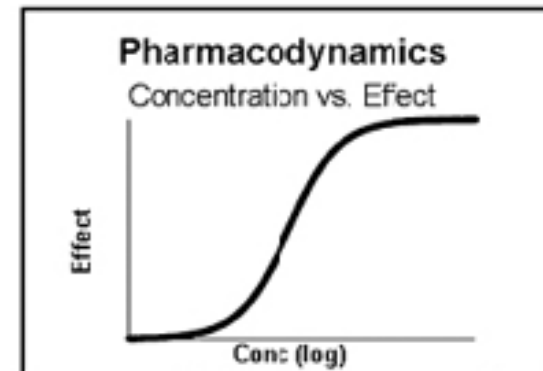
Guidance for Industry  
Immunogenicity Assessment for  
Therapeutic Protein Products

FDA Guidance for Immunogenicity:  
Patient and product specific factors, 2014  
Assay development and validation, draft 2009

# Biomarkers

## Biomarker assays allow us to understand what the drug does to the body

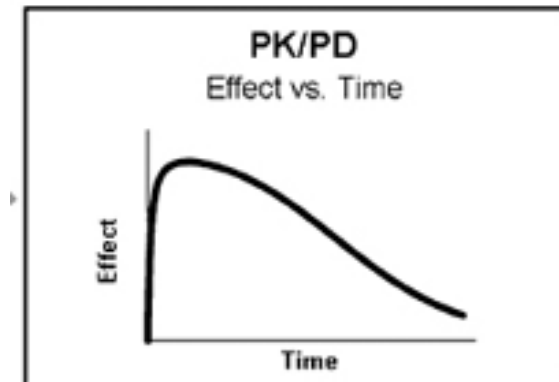
- Bioanalytical scientists establish strategies to develop, validate, and implement biomarker assays in support of drug development
- Biomarkers can range from x-rays to glucose measurements and can provide a surrogate end point of clinical relevance
- Ligand binding assays (ELISA to FACS) and LC/MS are classical quantitative platforms used to measure biomarkers in accessible matrices (blood/tissue)
  - Can be used to measure target levels (soluble or cellular)
  - Can be used to understand response to therapy; proximal and distal to site of action



## Appropriate measurement of relevant biomarkers at the right time from the right place is critical in drug development at every stage:

- The relationship between drug concentrations in circulation and a resulting pharmacological effect (PK/PD) provide valuable information concerning the safety and efficacy of a drug.

## The goal of biomarker application is to get the right therapy to the right patient at the right time



# Regulatory Agency Interactions

**AAPS Objective: Identify and influence key science policy and regulatory issues**

- Publish Industry White Papers *influencing world-wide regulatory agencies and bioanalytical community*
  - The AAPS Journal
  - AAPS Pharm SciTech
  - Pharmaceutical Research
- Comment on world-wide regulatory draft guidance's thereby *impacting the outcomes of regulatory policy (FDA/EMA/Canada/Columbia/China/Japan...)*
- Organize Crystal City Workshops (1990, 2000, 2006, 2007, 2014) presenting an opportunity for the *scientific and regulatory communities to come together to discuss best practices* within regulated bioanalysis
- Organize Conferences (National Biotech Conference and Annual Meeting) providing an *international forum for the exchange of knowledge* among scientists from Industry, Regulatory Agencies and Academia
  - LBABFG has **400 members from 22 countries** working in the BioPharma Industry



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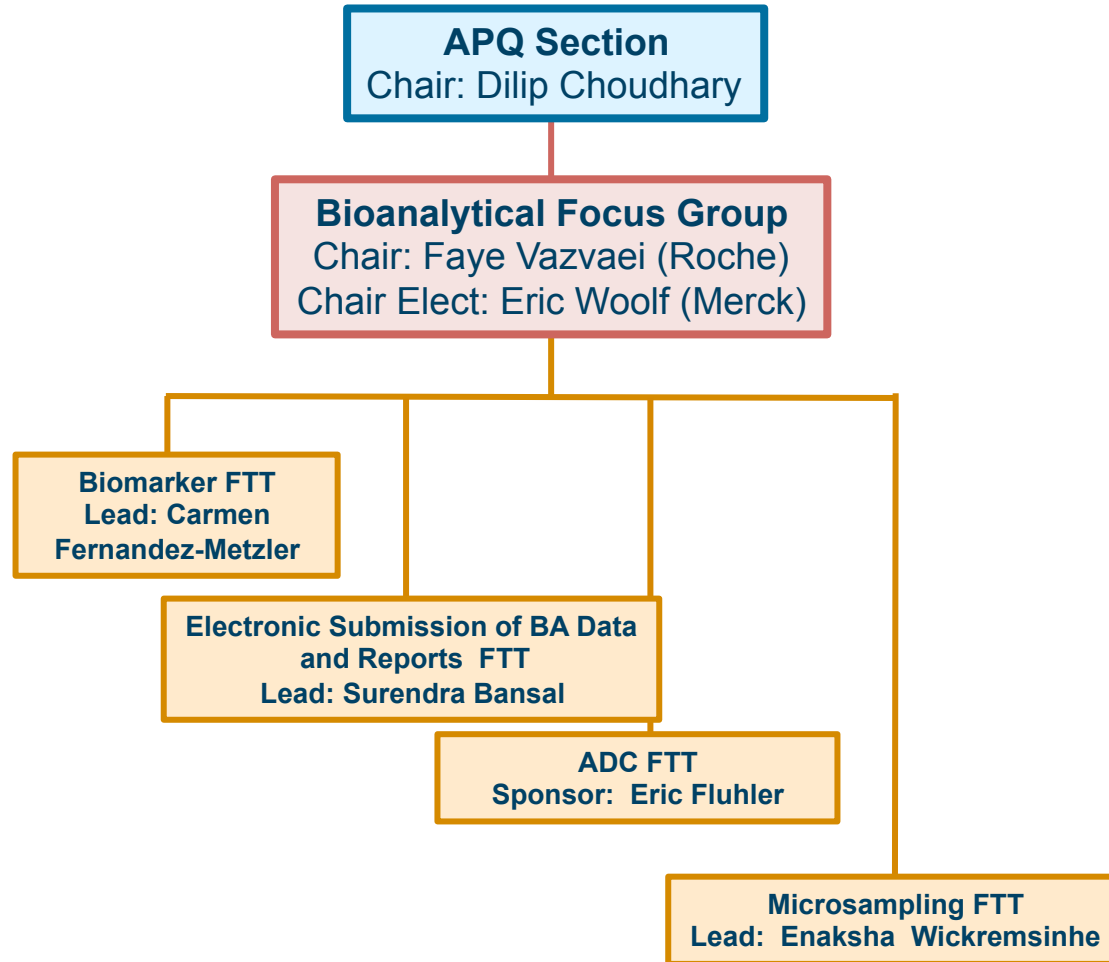
# Bioanalytical Focus Group

The Bioanalytical focus group has been in existence since 2000. The group focuses on chromatographic assays applied to quantitative and qualitative investigations of small and large molecules in biological matrices that support drug discovery and development. The modern bioanalytical laboratory utilizes a range of technologies and techniques which are constantly evolving. This focus group helps coordinate AAPS-supported programming and resources for its membership to help educate and inform of these developments.

## Goals

- Promote and coordinate AAPS programming initiatives around bioanalysis topics.
- Educate, inform and engage the bioanalytical community through programming, white papers, webinars and collective efforts of the Focus Topic Teams.
- Discuss issues that impact the development, validation and implementation of bioanalytical methods supporting PK and PD studies including emerging technologies and novel applications.
- Engage pharmaceutical scientists and regulators to develop best practices/ recommendations for bioanalysis and comment on regulatory developments and new draft guidance documents.
- Collaborate and work with other AAPS focus groups to achieve cross-functional goals.

# BFG within AAPS



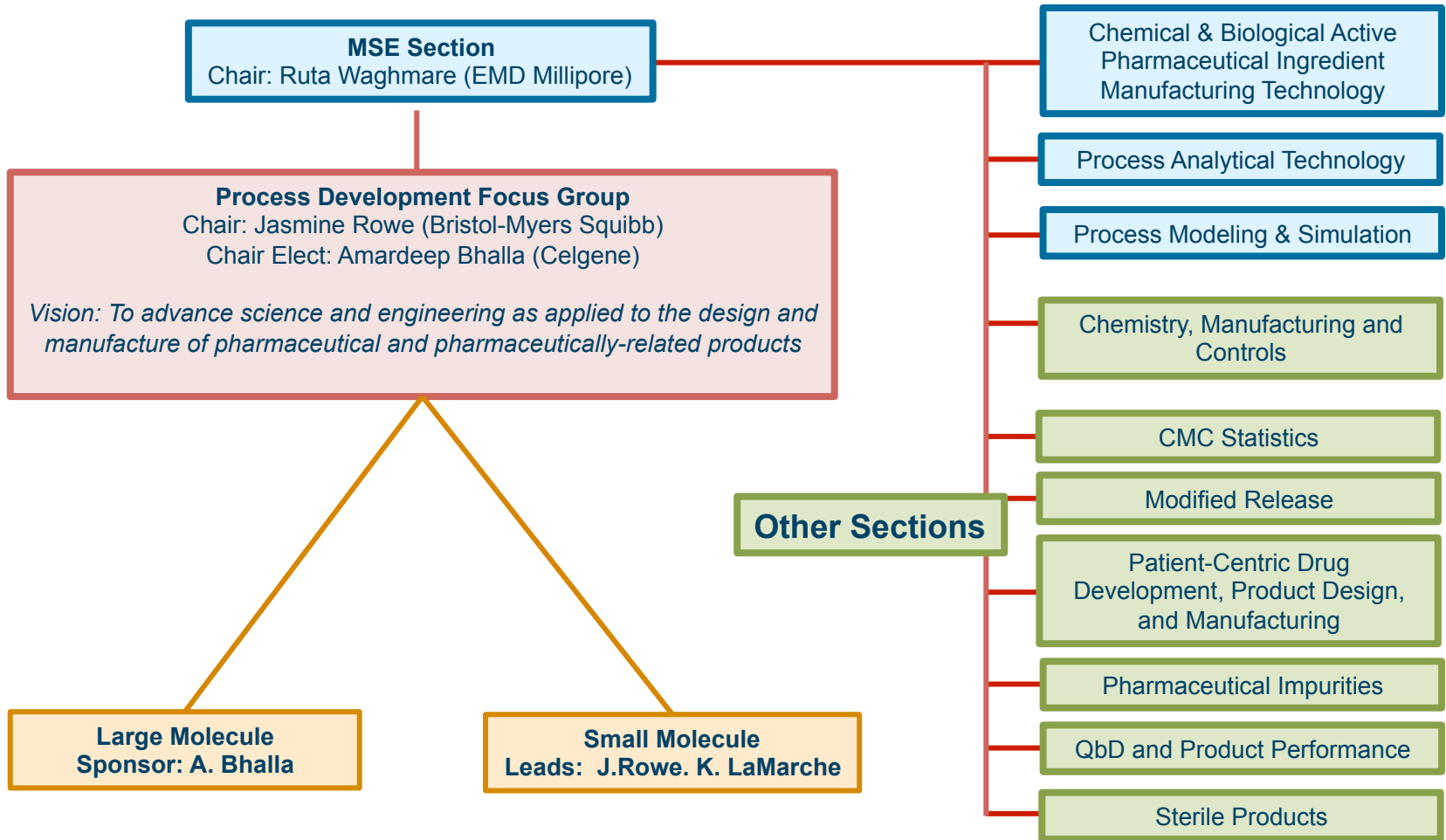
FTT = Focus Topic Team



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# PDFG within AAPS



## Mission

- Provide a forum for open interchange and dissemination of scientific knowledge
- Provide relevant programming content for organizational events to continuously advance reputation and caliber of the organization
- Foster an environment for graduate education and professional development through strong networking and membership interactions
- Collaborate with other sections and focus groups to advance the science of the industry
- Recognize excellence and achievement of its members through programming, publications

## Current Focus

- Application of **models** during product development and regulatory acceptance
- Facilitate **technology transfer** and **scale-up** activities
- Adoption of **novel technologies/ideas**
- Expand expertise from **small molecules** to include **biologics**

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**Development Research:** Biochemistry, *analytical*, pharmaceutical sciences, engineering, clinical trial management, statistics

**Manufacturing: Engineering,** biochemistry, *analytical*, operations

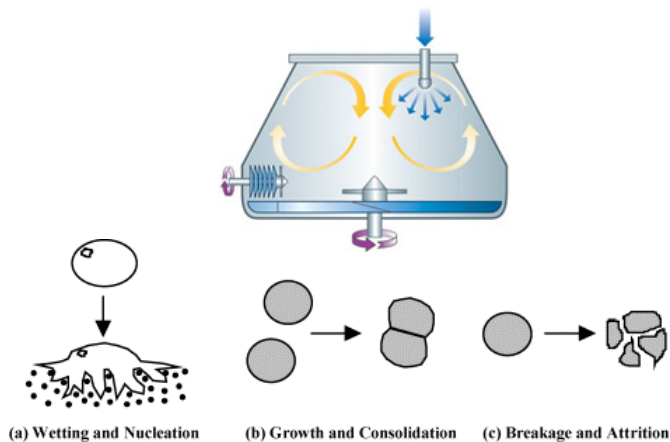
**Medical:** Clinical development, technical writing, regulatory, project management, pharmacovigilance, operations

Opportunities to enable early decisions with small amounts of drug substance

Earlier we can finalize paths forward, the quicker we can get products to market

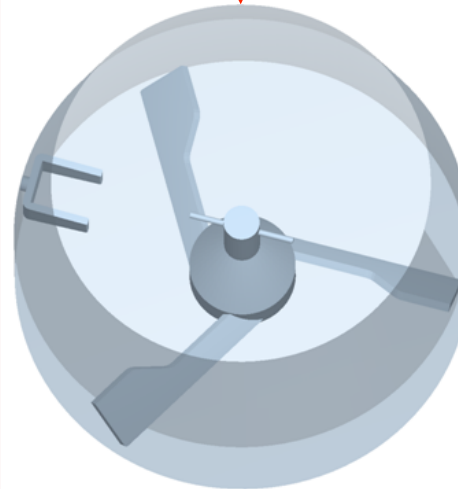
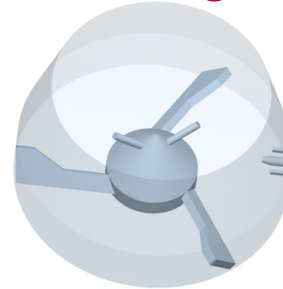
# Impact: Leveraging a Community to Advance Science

## Wet Granulation



- **Common unit operation for solids oral dose drug manufacturing**  
Prevents segregation, Improves flow of API,  
Tolerates large range of API material properties
- **Complex unit operation with several mechanisms at play**

0.25 L: Mfg A



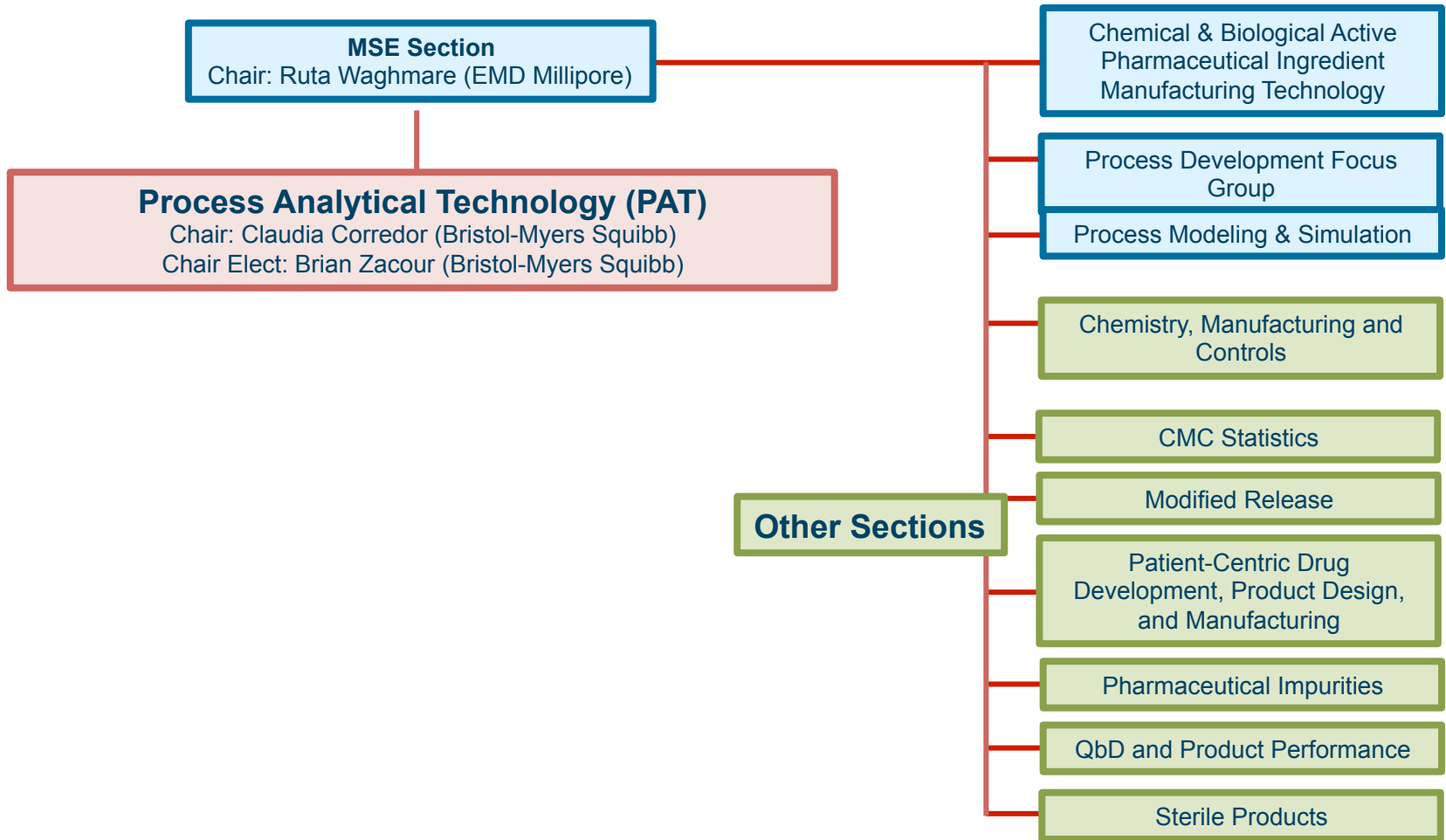
10 L: Mfg A



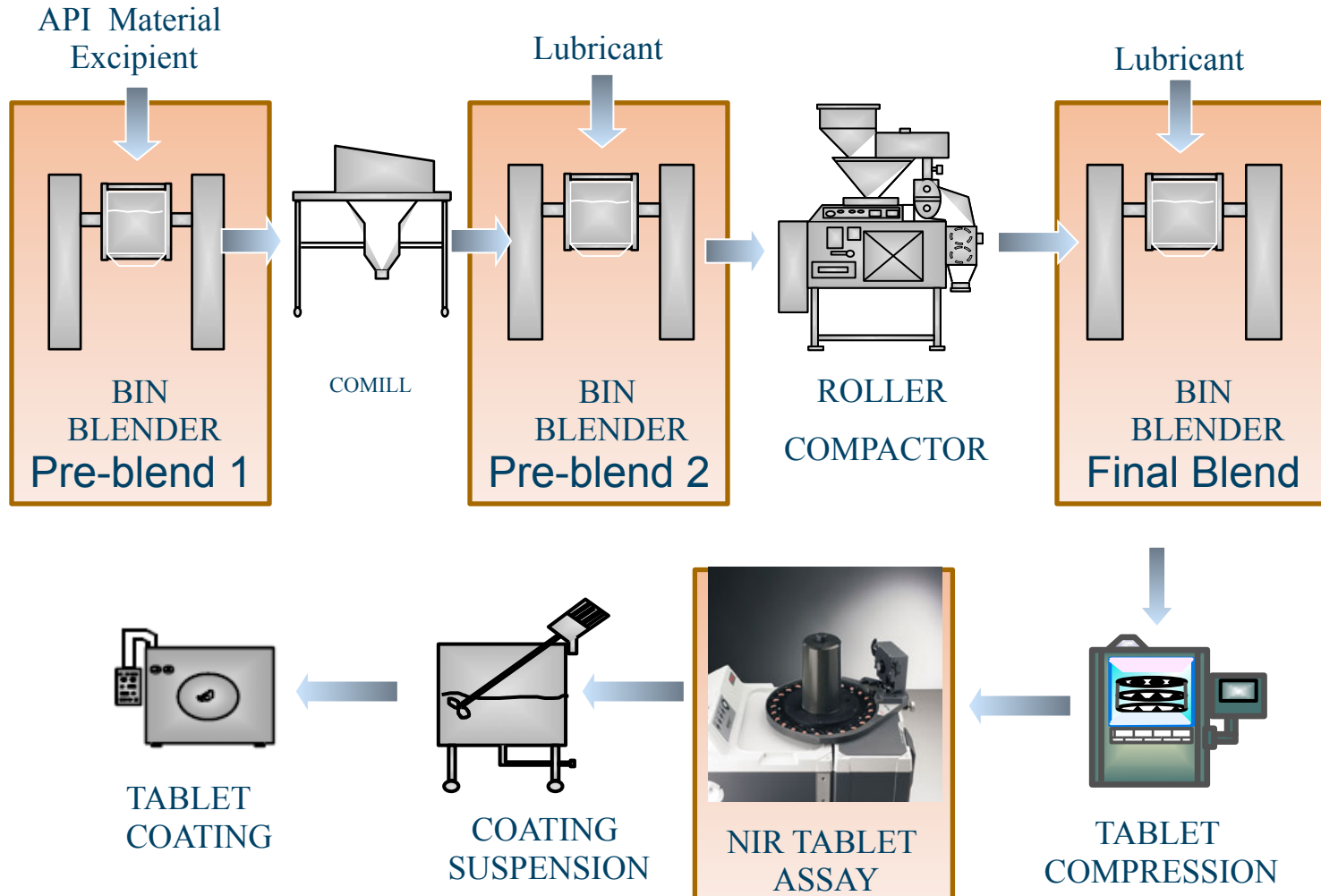
10 L: Mfg B

Continuous  
Manufacture

# PAT within AAPS



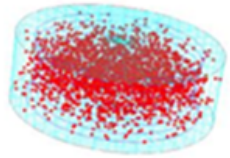
# PAT Tools in Manufacturing of Drugs



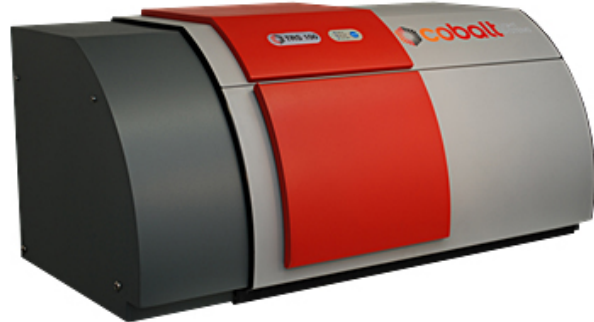
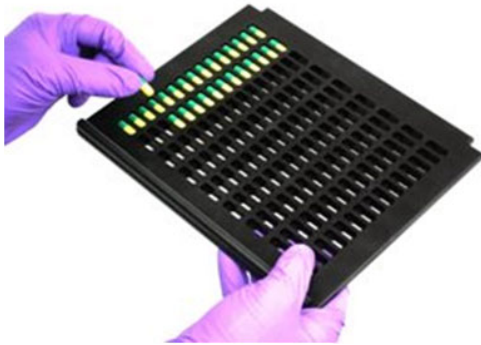
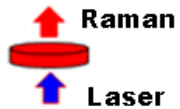
➤ PAT tools are routinely integrated into developing understanding, process monitoring and control strategies for drug product processes.



# PAT FG Mission: Industry, Regulatory Agencies and Academia in a Common Forum

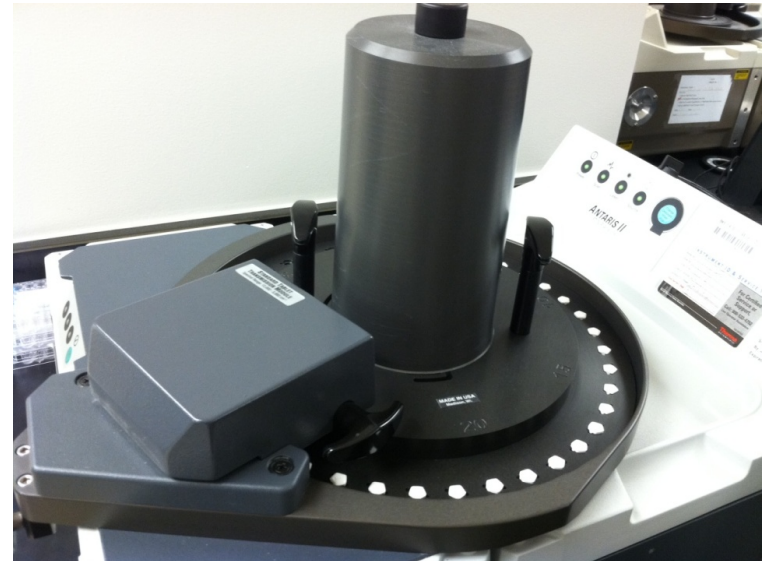


Transmission Raman



- At-line Raman tablet potency

- PAT FG provides a forum for discussion across industry, regulatory agencies, and academia for improved understanding, utilization and implementation of PAT



- At-line NIR tablet potency

- Exchanging emerging scientific and technical accomplishments and experiences and the latest regulatory information on PAT.

# Careers in Pharmaceutical Sciences

## Choosing the Right Discipline

- Academia
  - Independent work environment
  - Schedule flexibility
  - Lots of faculty positions due to current shortage
- Industry: Discovery, Development, Manufacturing, Medical
  - Bringing drugs to market
  - Team-oriented atmosphere
  - Can often see the bigger picture
- Regulatory
  - Unique environment with similarities to academia and industry
  - Protect public health by ensuring the safety and effectiveness of drugs
  - Opportunity to be a part of a world-class, science-based public health organization

# Skills and Education

## Skills most valued in the Pharma/Biotech Industry

- Scientific and Technical Excellence
- Leadership and Responsibility
- Teamwork and Communication
- Accepts Challenges and Risks

## Education and Training Options

- H.S. Diploma/Associates Degree-Technician
- B.S./M.S. in Pharmaceutical Sciences, Chemistry, Biology, Mathematics, Biomedical Engineering, IT, or related
- Pharm.D.
- Ph.D. in Pharmaceutical Sciences, Biochemistry, Biotechnology, or related
- Other: Marketing, Business, Advertising, Sales, Computer Science, etc.

## **AAPS Executive Council**

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Ankur Kulshrestha, [Ankur.Kulshrestha@bms.com](mailto:Ankur.Kulshrestha@bms.com)

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# Opportunities....

- Internship at Bristol-Myers Squibb:  
[http://www.bms.com/careers/university\\_recruitment/internships\\_co-ops/pages/default.aspx](http://www.bms.com/careers/university_recruitment/internships_co-ops/pages/default.aspx)
- Internship at Merck:  
[https://merck.taleo.net/careersection/merck\\_university\\_recruiting\\_career\\_section/jobsearch.ftl?lang=en#](https://merck.taleo.net/careersection/merck_university_recruiting_career_section/jobsearch.ftl?lang=en#)
- Post-doc opportunities at Merck:  
[https://merck.taleo.net/careersection/ext\\_merckunitedstates\\_en/jobsearch.ftl?lang=en&radiusType=K&location=294440130092&keyword=mrlpostdoc](https://merck.taleo.net/careersection/ext_merckunitedstates_en/jobsearch.ftl?lang=en&radiusType=K&location=294440130092&keyword=mrlpostdoc)