GDUFA Science and Research
Collaborating with the FDA Research Program

SPIE Photonics West

FDA Policies and Procedures: What Academic Investigators and Small Business Should Know

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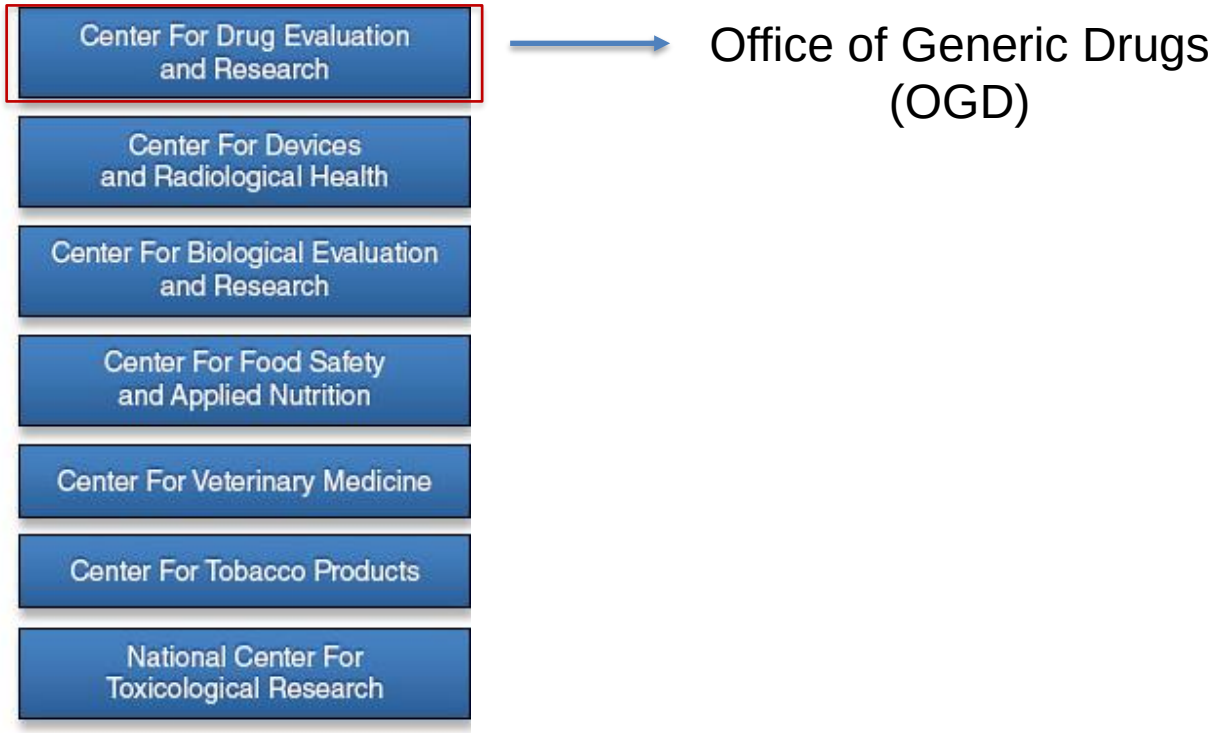
Disclaimer

This presentation reflects the views of the author and should not be construed to represent FDA's official views or policies.

FDA Organizational Structure



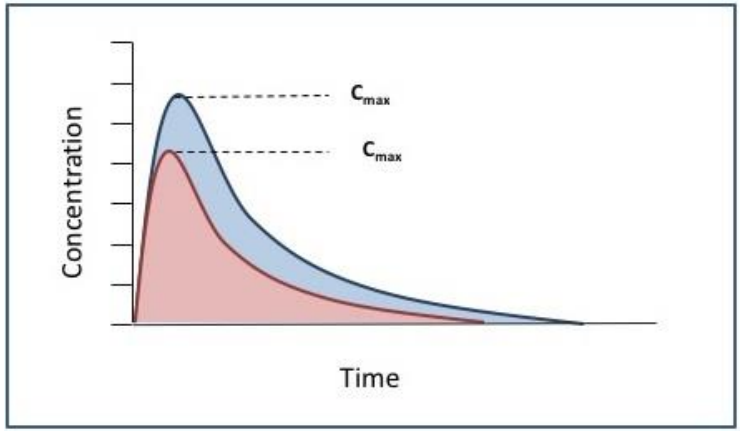
https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-generic-drugs

The Promise of Generic Drugs

- Generic drug products use the same active ingredient(s) and can be expected to have the same clinical effect and safety profile when administered under conditions specified in the labeling, as the brand-name (reference) listed drug products
- Generic drug products can be substituted for the reference listed drug product
- ….And they can cost less money

https://www.fda.gov/drugs/generic-drugs/generic-drug-facts

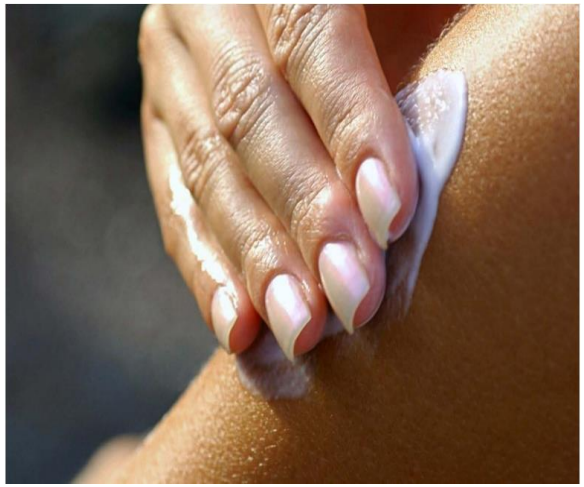
How are Generic Drugs Approved?



Bioavailability (BA) is assessed, and bioequivalence (BE) is typically established by showing that a generic drug product and the reference standard are similar in terms of their concentrations over time at the site of action (e.g., in the blood)

https://www.fda.gov/drugs/regulatory-science-action/impact-story-developing-new-ways-evaluate-bioequivalence-topical-drugs

Locally Acting Drug Products

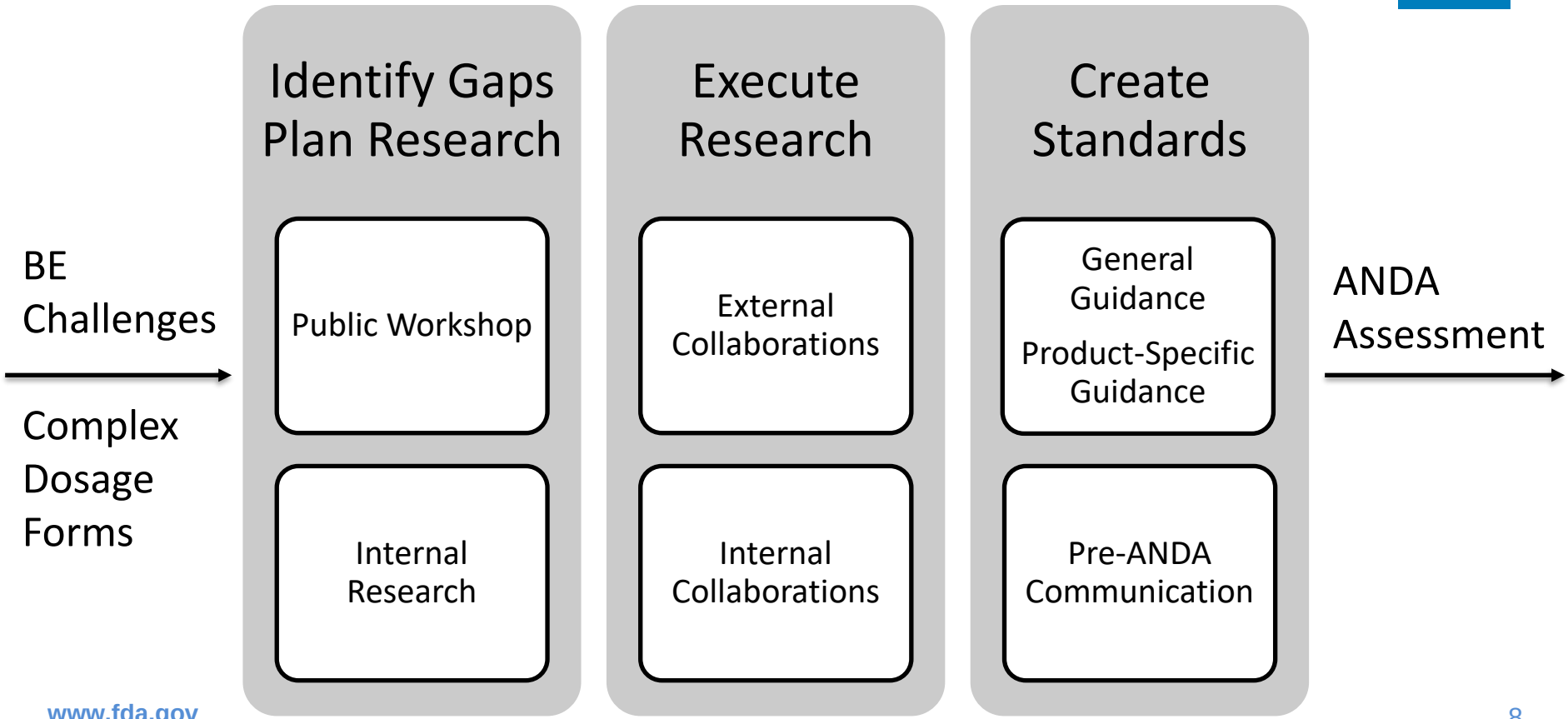


GDUFA

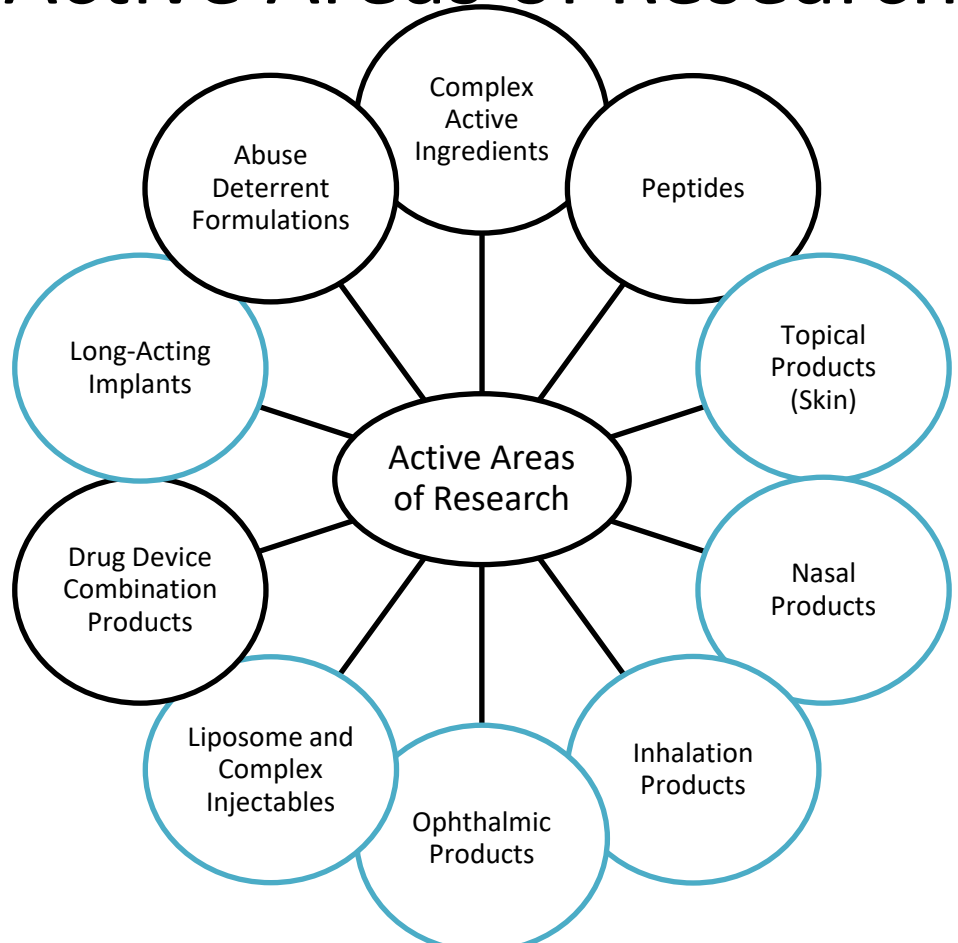
- The Generic Drug User Fee Amendments (GDUFA) was signed into law in July 2012, as part of the Food and Drug Administration Safety and Innovation Act (FDASIA)
- One out of numerous User Fee Programs that help the FDA to fulfill its mission of protecting the public health and accelerating innovation in the industry
- GDUFA is designed to speed the delivery of safe and effective generic drugs to the public and improve upon the predictability of the review process
- One unique feature of GDUFA is the Regulatory Science and Research Program ~ $20 million annually
- GDUFA must be reauthorized every 5 years (currently in GDUFA III)

https://www.fda.gov/industry/fda-user-fee-programs
https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments

GDUFA Science and Research Program



Active Areas of Research



Topical Drug Products (Skin)

Cutaneous Pharmacokinetics (PK)

- Microdialysis (dMD) and Open Flow Microperfusion (dOFM) directly measure the in vivo rate and extent of drug BA at/near the site of action in the skin

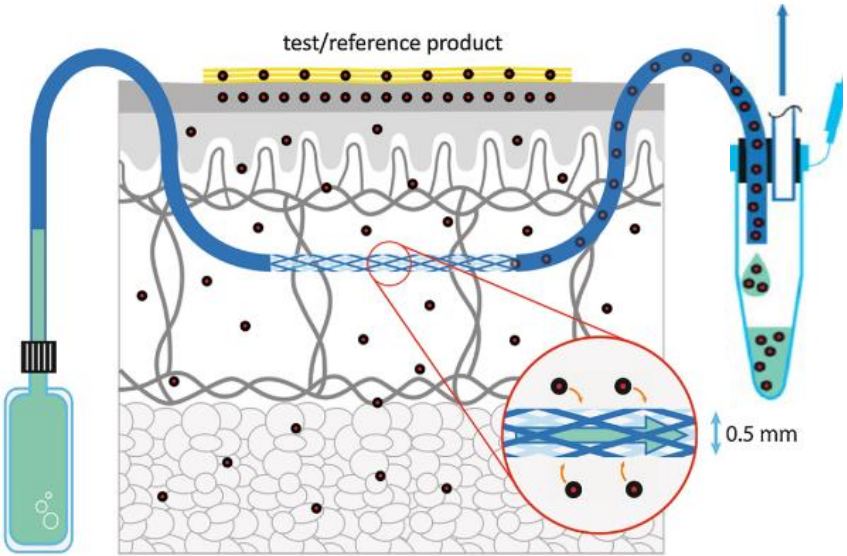
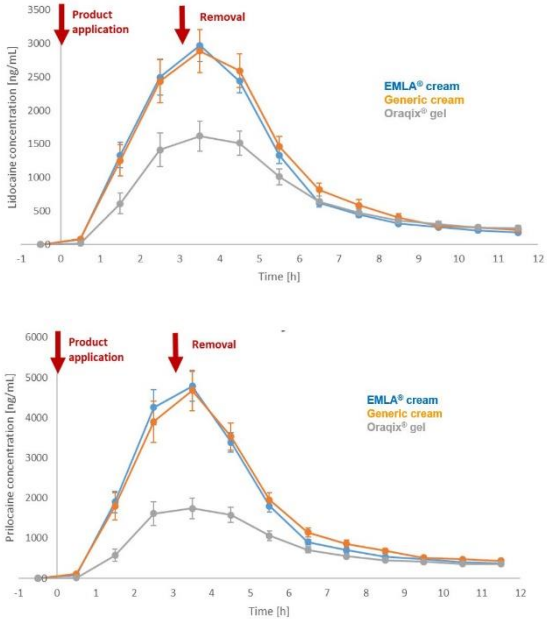


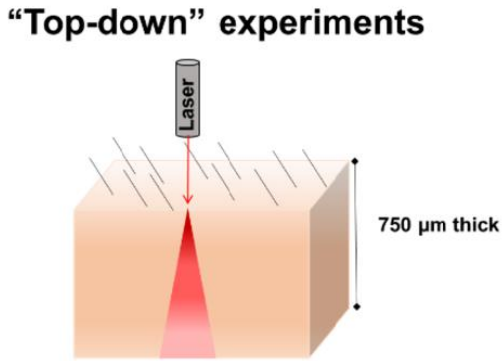
Image provided courtesy of Dr. Frank Sinner, Joanneum Research

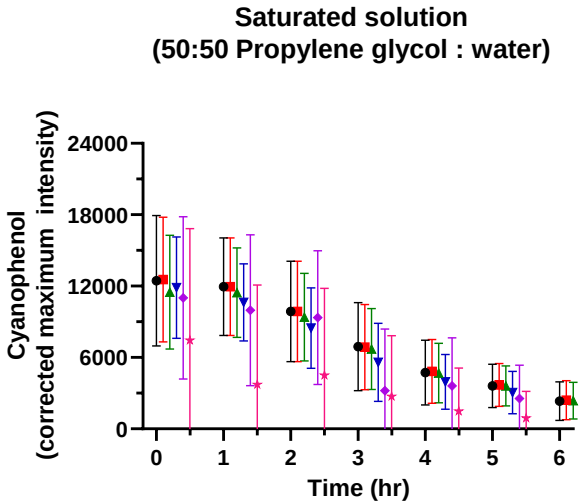


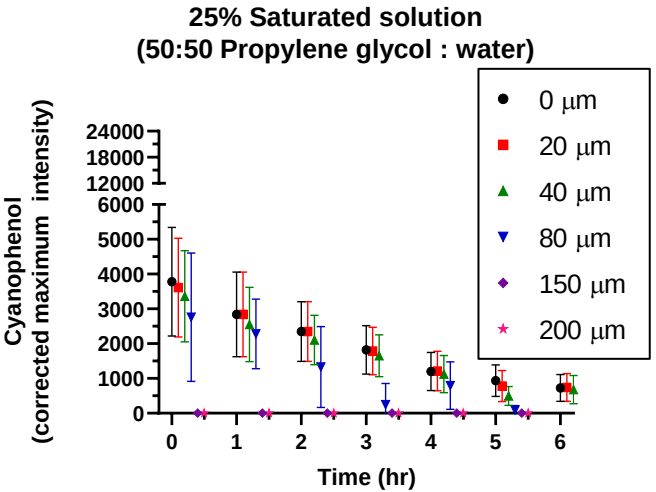
Dr. Frank Sinner associated with FDA funding for award U01-FD005861

Cutaneous PK

Confocal and Simulated Raman Spectroscopy can directly measure the rate and extent of drug BA at/near the site of action in the skin.



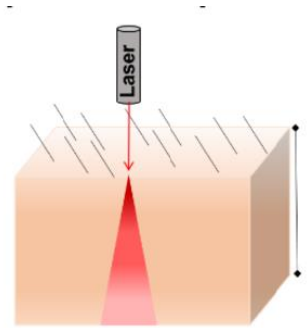


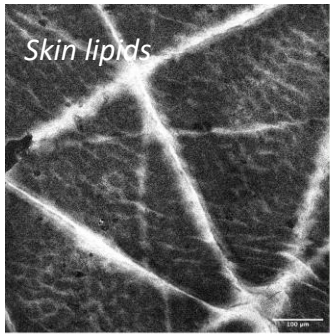


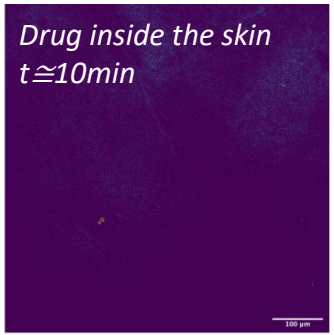
Dr. Richard Guy associated with FDA funding for award U01FD0006533

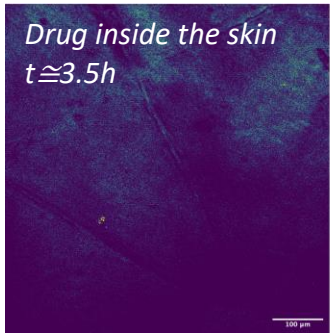
Cutaneous PK

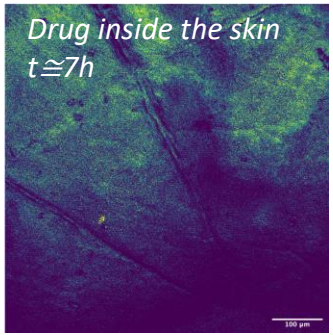
Confocal and Simulated Raman Spectroscopy can directly measure the rate and extent of drug BA at/near the site of action in the skin.

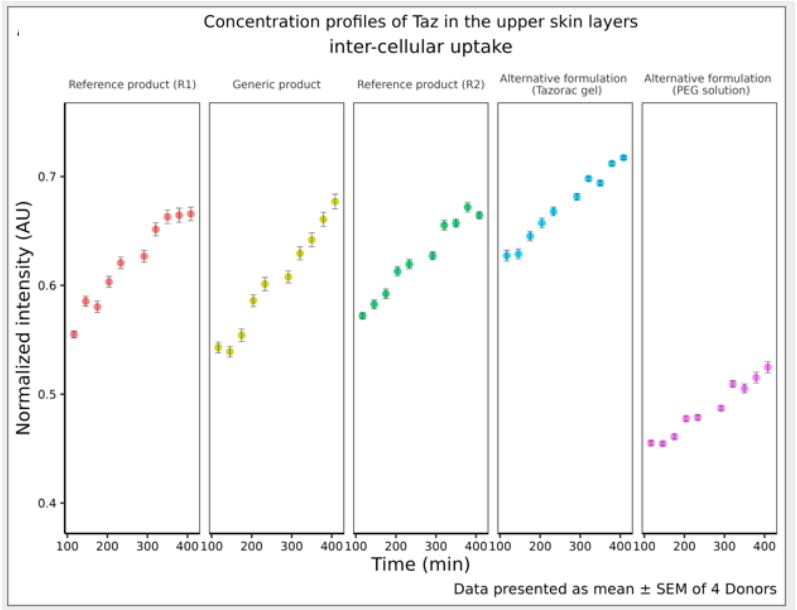






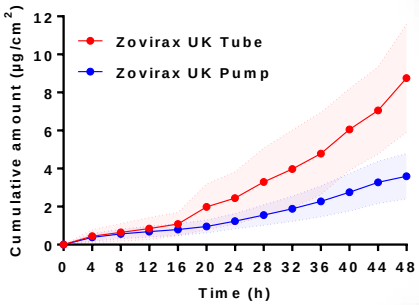






Dr. Conor Evans associated with FDA funding for award U01FD0006698

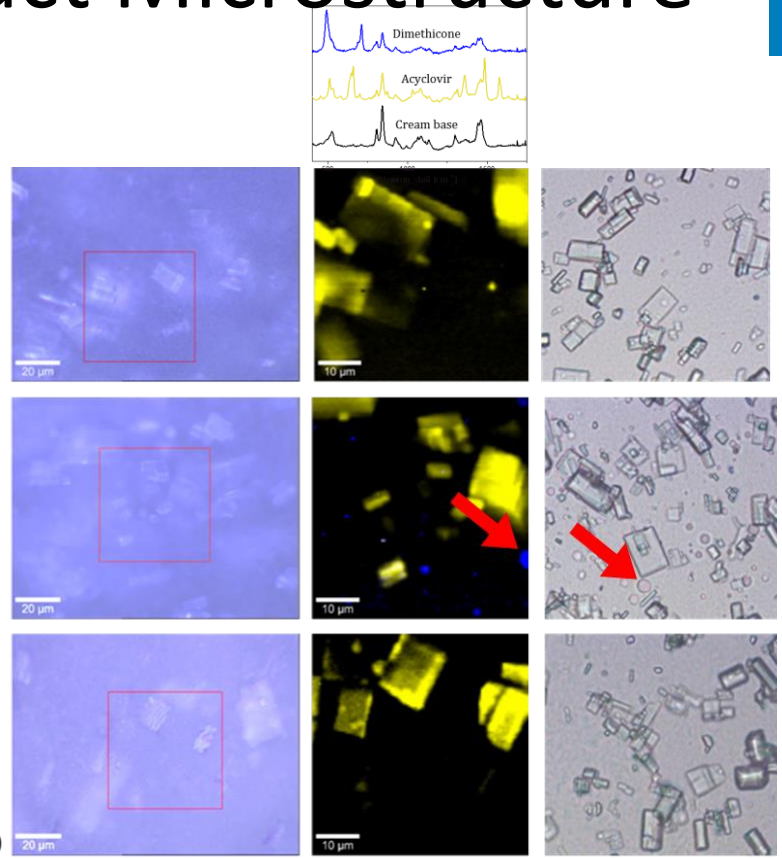
Understanding Product Microstructure



Zovirax® UK
Tube

Zovirax® UK
Pump

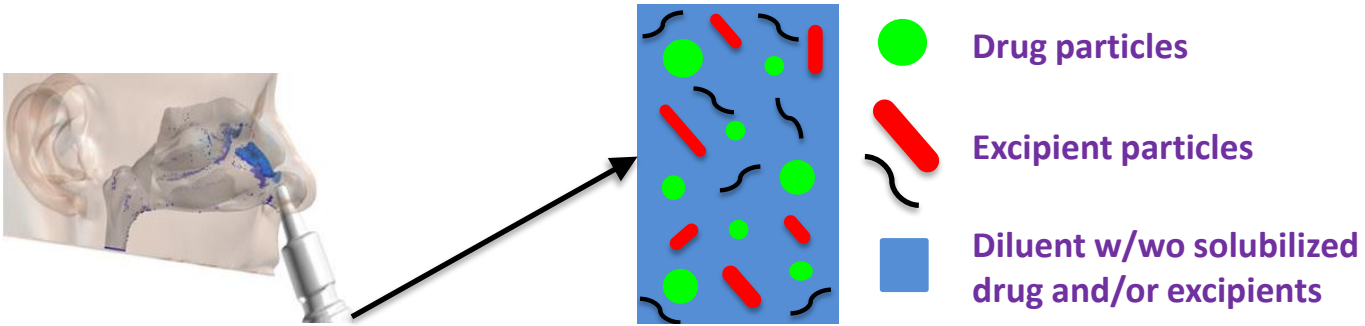
Zovirax® UK
Pump
(from inside container)



Prof. Michael Roberts associated with FDA funding for award U01-FD005226

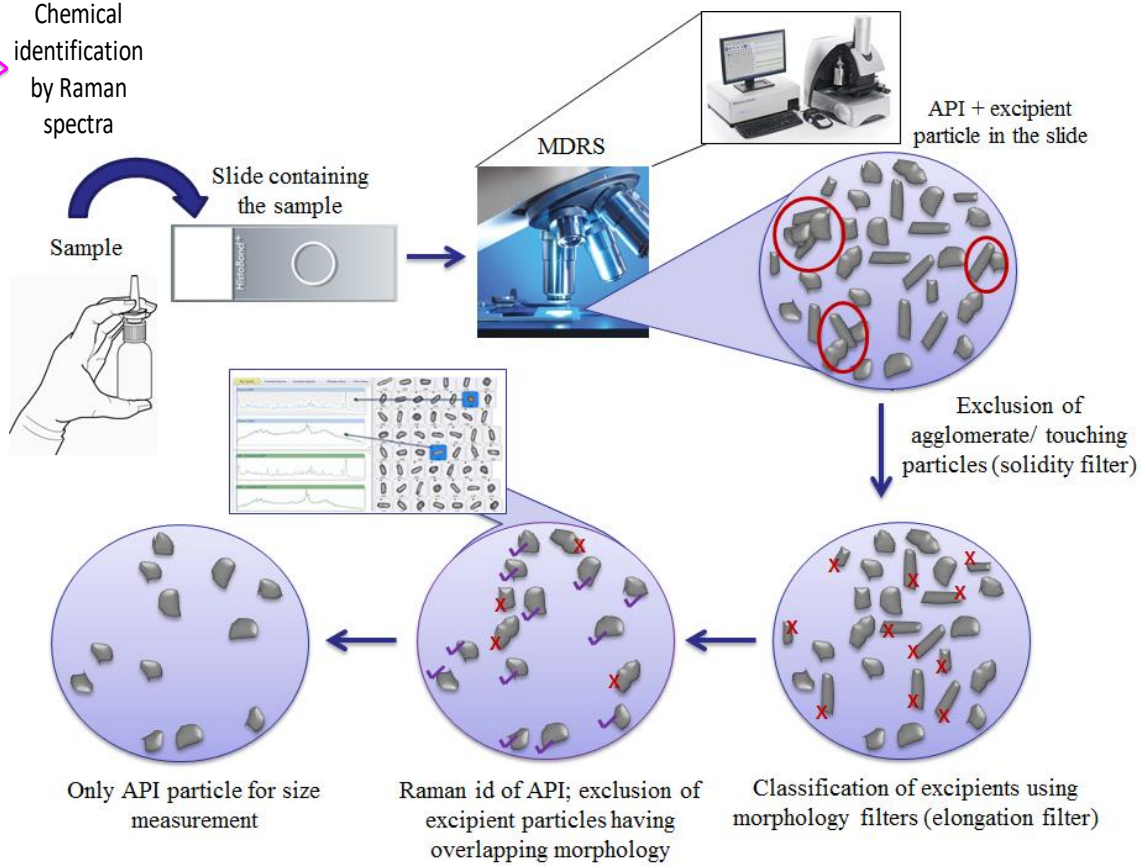
Orally Inhaled and Nasal Drug products (OINDP)

Nasal Suspension Sprays



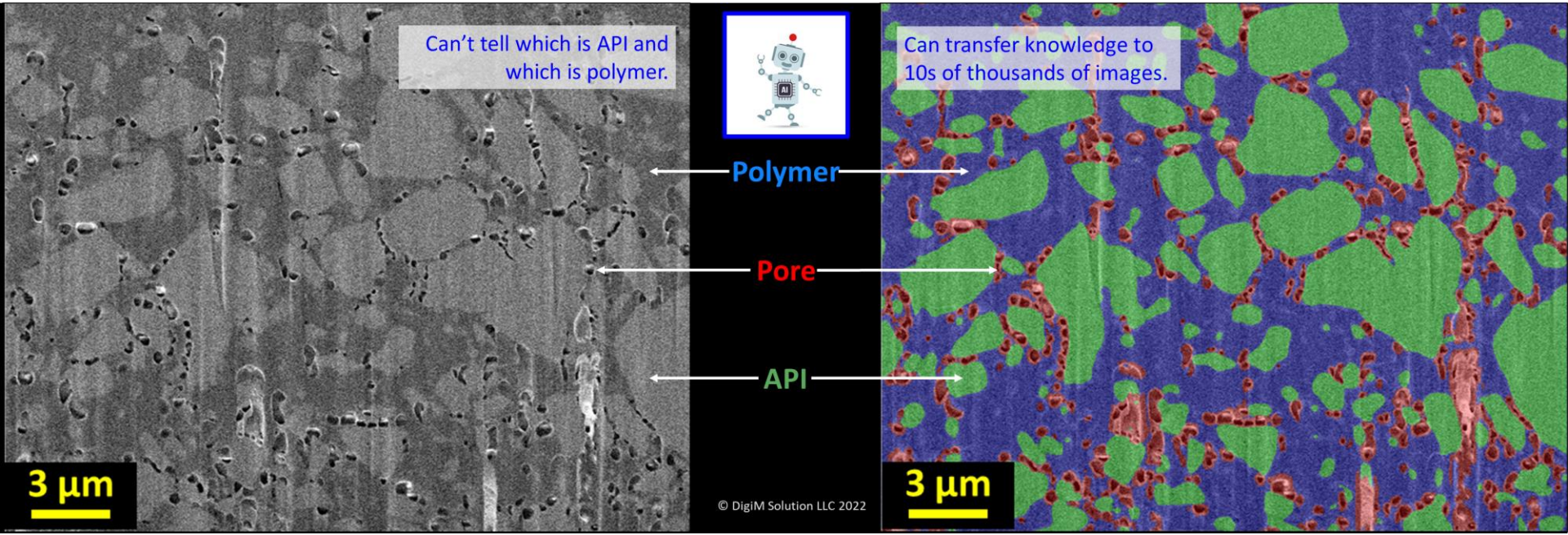
- Drug particle size distribution (PSD) in suspension formulations has the potential to influence the rate and extent of drug availability to nasal sites of action and systemic circulation
- Inability to adequately characterize drug PSD in aerosols and sprays using common analytical methods

Morphologically-Directed Raman Spectroscopy



Ophthalmic/Complex Injectables/Long-Acting Drug Products

Imaging and Artificial Intelligence



Dr. Shawn Zhang (DigiM) associated with FDA funding for award U01-FD005226

Summary

- The GDUFA regulatory science and research program is a model for research programs at the FDA
- The goal of the GDUFA regulatory science and research program is to facilitate the development of tools that can be utilized to facilitate drug development/establish BE and thereby enhance the availability of generic topical dermatological drug products
- We want to collaborate with you

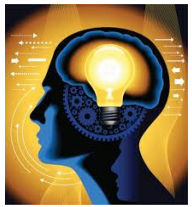
Quick References

- Research Priorities
  - https://www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects
- Outcomes
  - https://www.fda.gov/drugs/generic-drugs/generic-drug-research-publications-resources
- Collaborations
  - https://www.fda.gov/drugs/generic-drugs/generic-drug-research-collaboration-opportunities

https://www.fda.gov/drugs/generic-drugs/generic-drug-research-priorities-projects

Partnering with the FDA

- Regulatory Science Extramural Research and Development Projects
  - FDA welcomes research proposals for Grants/ Contracts/ Etc.
  - Generic Drug Regulatory Science Initiatives Public Workshop, Summer, 2023
  - Postdoctoral Fellowship Opportunities- https://orise.orau.gov/fda/



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https://www.fda.gov/drugs/generic-drugs/science-research

Acknowledgements

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Research Collaborators

Collaborations within FDA

All of our collaborators within the GDUFA Regulatory Science Research Program

U.S. FOOD & DRUG ADMINISTRATION

Thank You

Priyanka Ghosh, Ph.D.
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