

A Brief Perspective on the Role of Bioanalysis

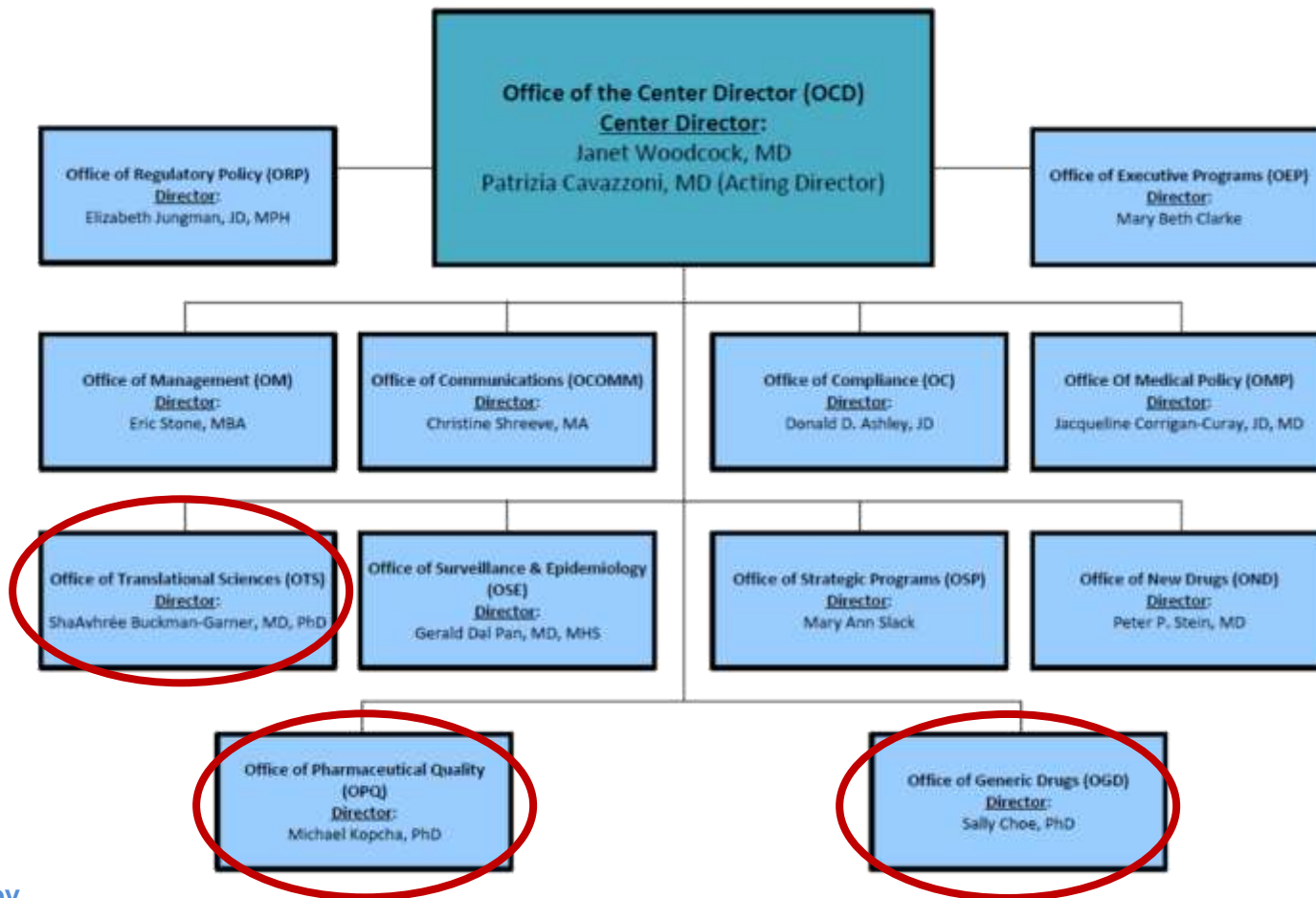
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CDER | US FDA

[Regulated Bioanalysis Workshop: Requirements and Expectations] – June 30, 2020





Some forces impacting the future of drug development

- COVID-19
- International regulatory convergence
- Advanced manufacturing
- Rise of biosimilars
- New science and technology
- Digital revolution/Information Technology/Automation
- Drug costs

Key Points

- Bioanalysis is the foundation that supports sound drug development
- Sample preparation and method validation are critical to demonstrate performance and reliability of analytical results
- We have to be open to new approaches/innovation
- We must have clear standards and expectations
- We have to be receptive to continued dialog and transfer of knowledge on science and technology between stakeholders

How do we foster enhanced collaboration?



- Workshops and Webinars
- Standard regulatory meeting interactions
- Academic Fellowships/Sabbaticals/Experiential Opportunities
- Critical Path Innovation Meetings (CPIM)

To learn more about CPIM



Critical Path Innovation Meetings

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

April 2016
Draft

Video on the Critical Path Innovation Meeting (CPIM) Program



FDA's Center for Drug Evaluation and Research developed this video to provide stakeholders with a better understanding of the Critical Path Innovation Meeting (CPIM) program including goals of the program, how to request a CPIM, topics and outcomes of past CPIMs, and where to find additional resources.



[Download Podcast](#) | [Transcript](#) | [Slides](#)

<https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/critical-path-innovation-meetings-cpim>

Today's Session

- All critical bioanalysis requires evaluation through review, research and inspection
- The more our stakeholders know how about how we operate and what we need, will further enhance the application review and inspection process



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