A Brief Perspective on the Role of Bioanalysis

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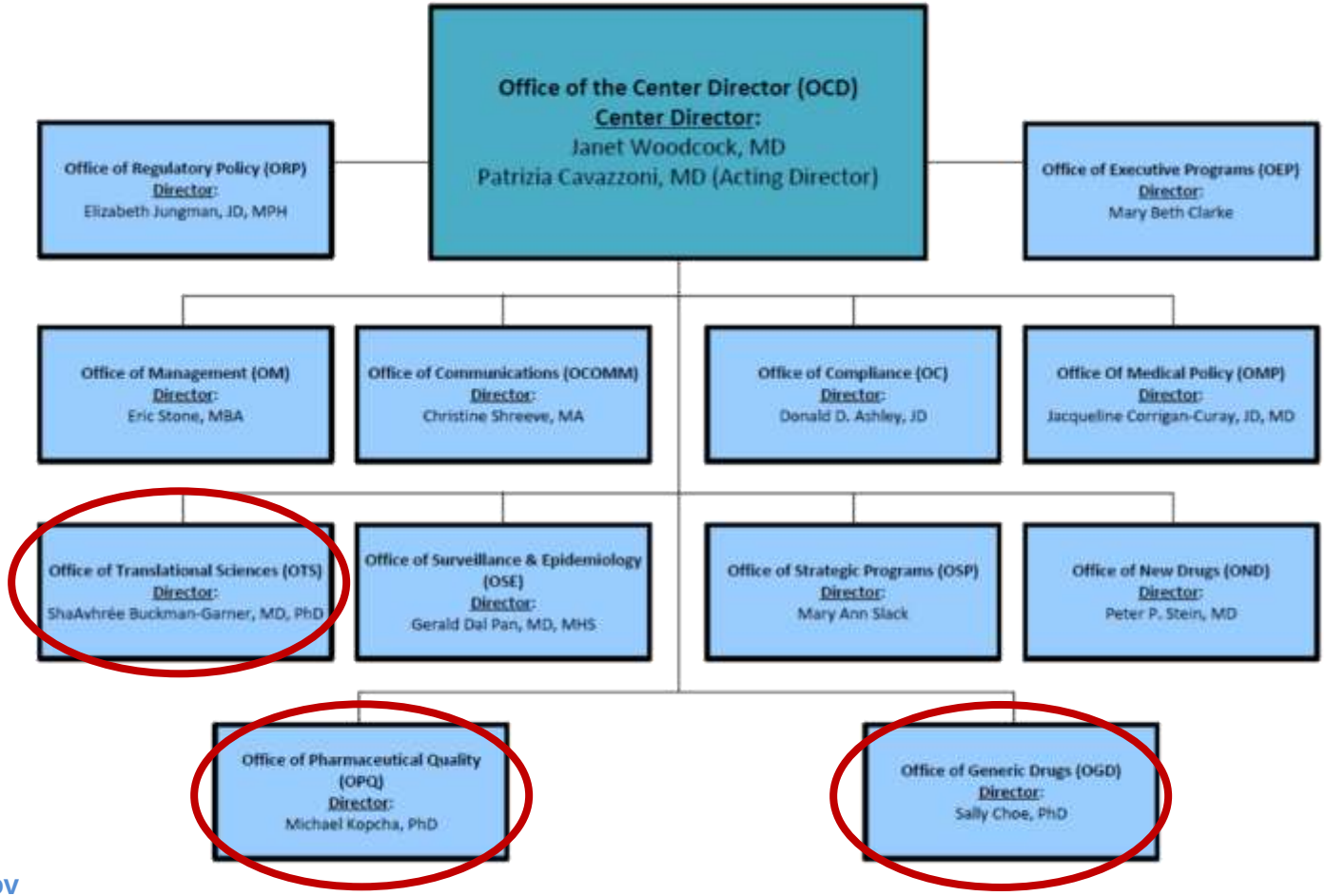
CENTER FOR DRUG EVALUATION AND RESEARCH



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

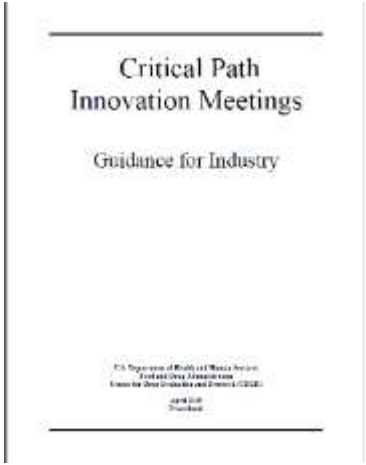
Key Points

- 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



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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