FDA-CRCG Workshop on Mastering Particle Size Analysis: A Step-By-Step Illustration of Techniques and Best Practices

Public Workshop
September 23-24, 2025
Agenda

Day 1 September 23

8:30 AM – 8:35 AM **Welcome and Opening Remarks**
Anna Schwendeman, PhD Co-Director, CRCG

8:35 AM – 8:55 AM **FDA Opening Remarks and Workshop Overview**
Xiaoming Xu, PhD Director, DPQR V, OPQR, OPQ, FDA

Session 1: Dynamic Light Scattering Theory, Practice, and Regulatory Perspectives
This session provides a comprehensive overview of DLS technology, exploring its fundamental principles and practical applications in particle size analysis. Industry and regulatory scientists will delve into the current challenges associated with analyzing and assessing particle size studies, particularly in the context of supporting regulatory approvals. The session will also cover critical aspects of method validation and highlight common deficiencies observed in regulatory submissions, offering valuable insights for both researchers and industry professionals.

8:55 AM – 9:40 AM ***Dynamic Light Scattering Theory and Practice***
Jeffrey Clogston, PhD Principal Scientist, Physicochemical Characterization Section Head, NCL

9:40 AM – 9:55 AM ***Regulatory Perspectives: Method Validation and Common Deficiencies***
William Smith, PhD Research Scientist, DPQR V, OPQR, OPQ, FDA

Session 2: Vendor Perspectives for DLS
In this session, seven DLS instrument vendors will present rapid-fire overviews of their latest technical developments and measurement best practices. These presentations will focus on innovative solutions to overcome common issues in particle sizing. Speakers will discuss critical considerations that guide users in selecting and operating DLS equipment effectively, providing real-world examples to illustrate the context of use.

9:55 AM – 10:00 AM ***Speaker Introductions***
Bin Qin, PhD Senior Staff Fellow, DTP I, ORS, OGD, FDA

10:00 AM – 10:10 AM ***Studies of Data Quality for Dynamic and Static Light Scattering***
Matthew McGann, MS Applications, Product Management, Mktg. Specialist, Bettersize Instruments

10:10 AM – 10:20 AM ***HORIBA and Complete DLS***
Jeff Bodycomb, PhD Product Line Manager, HORIBA

10:20 AM – 10:40 AM ***Coffee Break***

10:40 AM – 10:50 AM ***The Benefits of Spatially Resolved Dynamic Light Scattering (SR-DLS)***
Carl Schuurmans, MS Associate Director, Applied Process Analytical Technologies, Inprocess-LSP

10:50 AM – 11:00 AM ***Overcoming Common Issues in Particle Sizing: Latest Innovations from the Malvern Zetasizer Advance***
Jonathan Mehtala, PhD Senior Application Scientist, Malvern Panalytical

11:00 AM – 11:10 AM ***Rapid Fire-Dynamic Light Scattering***
Prashun Roy, PhD Application Scientist, Microtrac, part of Verder

11:10 AM – 11:20 AM ***Sizing by Rotating Angles to Provide a Complete Perspective on DLS***
Kevin Lance, PhD Director of Product Management, Unchained Labs

11:20 AM – 11:30 AM ***Dynamic Light Scattering: Perspectives on Method Development and Validation***

Collin Britten, PhD Field Application Scientist, Waters/Wyatt Technology

11:30 AM – 12:15 PM ***Q&A Session with Panel***

Moderator:	**Bin Qin, PhD**	Senior Staff Fellow, DTP I, ORS, OGD, FDA
Panelists:	**Jeff Bodycomb, PhD**	Product Line Manager, HORIBA
	Collin Britten, PhD	Field Application Scientist, Waters/Wyatt Technology
	Jeffrey Clogston, PhD	Principal Scientist, Physicochemical Characterization Section Head, NCL
	Kevin Lance, PhD	Director of Product Management, Unchained Labs
	Matthew McGann, MS	Applications, Product Management, Mktg. Specialist, Bettersize Instruments
	Jonathan Mehtala, PhD	Senior Application Scientist, Malvern Panalytical
	Prashun Roy, PhD	Application Scientist, Microtrac, part of Verder
	Carl Schuurmans, MS	Associate Director, Applied Process Analytical Technologies, Inprocess-LSP
	William Smith, PhD	Research Scientist, DPQR V, OPQR, OPQ, FDA
	Xiaoming Xu, PhD	Director, DPQR V, OPQR, OPQ, FDA

12:15 PM – 1:10 PM ***Lunch Break***

Session 3: DLS Equipment Demonstrations (In-Person Only)

This hands-on session offers in-person attendees a unique opportunity to work directly with DLS equipment vendors. Participants will be divided into small groups, rotating through demonstrations of suitable particle size study procedures. Vendor representatives will guide attendees through the intricacies of method development, highlighting common pitfalls and how to avoid them. This practical experience will provide invaluable insights into the nuances of different DLS systems and their applications in complex generic drug development.

1:10 PM –1:55 PM ***Session 3A Demonstrations***

Vendor	Sample
Bettersize	cyclosporine
HORIBA	cyclosporine
Inprocess	iron sucrose
Malvern	phytonadione
Microtrac	iron sucrose
Unchained Labs	phytonadione
Waters/Wyatt Technology	Iron sucrose

1:55 PM – 2:40 PM ***Session 3B Demonstrations***

Vendor	Sample
Bettersize	phytonadione
HORIBA	phytonadione
Inprocess	phytonadione
Malvern	iron sucrose
Microtrac	cyclosporine
Unchained Labs	iron sucrose
Waters/Wyatt Technology	cyclosporine

2:40 PM – 2:50 PM ***Coffee Break***

Session 4: Small Working Group Sessions (In-Person Only)

In this collaborative session, attendees will work in small groups to tackle real-world challenges in particle size analysis. Guided by experienced moderators, participants will engage in in-depth discussions on multiple topics including measurement considerations, method development, method transfer, validation strategies, data analysis techniques and reporting.

2:50 PM – 4:10 PM ***Topic 1. Measurement (Before and During the Process)***

Focus: Purpose, method selection, equipment variability, robustness

4:10 PM – 5:30 PM ***Topic 2: Data Analysis, Comparison, and Reporting (After Measurement)***

Focus: Statistical comparison, definitions of accuracy, reporting standards

Day 2 September 24

8:30 AM – 8:40 AM *Day 1 Summary*
Bin Qin, PhD Senior Staff Fellow, DTP I, ORS, OGD, FDA

Session 5: Laser Diffraction (LD) Theory and Practice
This session provides a comprehensive introduction to LD technology, exploring its theoretical foundations and practical applications in particle size analysis. Expert speakers will delve into the current challenges associated with LD-based particle size studies, offering insights into best practices and potential pitfalls. Attendees will gain a deeper understanding of LD principles, enabling them to make informed decisions when selecting and implementing this technology in their research or industrial settings.

8:40 AM – 8:45 AM *Speaker Introductions*
Nicholas Holtgrewe, PhD Chemist, DPQR II, OPQR, OPQ, FDA

8:45 AM – 9:30 AM *Laser Diffraction-How Does It Work and Challenges with Measurement*
Alan F. Rawle, PhD Emeritus Expert in Particle Sizing and Analysis

Session 6: Industry Perspectives on Particle Size Measurement
Industry leaders will share their experiences and insights on the challenges faced in developing generic products, with a focus on particle size measurement. Speakers will discuss critical aspects such as technology selection, method development, and validation processes. The session will also explore the emerging role of artificial intelligence and machine learning in knowledge management for regulatory submissions. A key component of this session will be a discussion on potential hurdles in preparing submission packages and areas where additional FDA guidance could be beneficial, fostering a productive dialogue between industry and regulatory perspectives later in the workshop.

9:30 AM – 10:15 AM *Unresolved Challenges in Determining API Particle Size Distribution in Complex Suspensions Using Laser Diffraction*
Jernej Grmaš, PhD Head of Physical Analytics, Lek Pharmaceuticals d.d. (Sandoz)

Challenges in DLS-Based Method Development: The Issue of Heterogeneity
Rama Subba Reddy K, MS Analytical Expert-ACT Lab-Polymorphism & Nanosizing, Dr. Reddy's Lab. Ltd

Bridging the Gap Harmonizing Laser Diffraction PSD with Real-Life Results and Regulatory Requirements
Yousif Ayoub, PhD Director, Head of Analytical Development, KFS R&D, Teva Pharmaceuticals, Inc.

10:15 AM – 10:30 AM *Hurdles/Issues/Challenges with Regulatory Package for Submission-Generic Industry Perspective*
Bernard Domnic, MS Director, Regulatory Affairs, Teva Pharmaceuticals, Inc.

10:30 AM – 10:45 AM *Coffee Break*

Session 7: Vendor Perspectives for LD
This session mirrors the format of Session 2, focusing on LD technology. Four LD instrument manufacturers will deliver presentations highlighting their latest technical developments and measurement best practices. These talks will address common challenges in particle sizing and offer innovative solutions. Speakers will discuss critical factors that guide users in selecting and operating LD equipment effectively, providing practical examples to illustrate real-world applications. The session will conclude with a panel discussion, allowing attendees to engage with experts and explore the topics covered in greater depth.

10:45 AM – 10:50 AM *Speaker Introductions*
William Smith, PhD Research Scientist, DPQR V, OPQR, OPQ, FDA

10:50 AM – 11:00 AM *Complete the Picture: Why Combining Laser Diffraction with Image Analysis Is the New Standard in Particle Characterization*
Kiwan Park, BS, MBA Sales Manager, Bettersize Instruments

11:00 AM – 11:10 AM *HORIBA and the Three Rs of Laser Diffraction: Repeatable, Reliable, and Robust*
Jeff Bodycomb, PhD Product Line Manager, HORIBA

11:10 AM – 11:20 AM *Streamlining Sample Analysis for Laser Diffraction: Techniques and Best Practices*
Dan Beach, BS, MBA Team Leader, Small Molecule Pharmaceuticals, Malvern Panalytical

11:20 AM – 11:30 AM *Rapid Fire-Laser Diffraction*
Matthew Elmer, BS, MEng Application Scientist, Microtrac, part of Verder

11:30 AM – 12:15 PM	***Q&A Session with Panel***	
Moderator:	**William Smith, PhD**	Research Scientist, DPQR V, OPQR, OPQ, FDA
Panelists:	**Yousif Ayoub, PhD**	Director, Head of Analytical Development, KFS R&D, Teva Pharmaceuticals, Inc.
	Dan Beach, BS, MBA	Team Leader, Small Molecule Pharmaceuticals, Malvern Panalytical
	Jeff Bodycomb, PhD	Product Line Manager, HORIBA
	Bernard Domnic, MS	Director, Regulatory Affairs, Teva Pharmaceuticals, Inc.
	Matthew Elmer, BS, MEng	Application Scientist, Microtrac, part of Verder
	Jernej Grmaš, PhD	Head of Physical Analytics, Lek Pharmaceuticals d.d. (Sandoz)
	Kiwan Park, BS, MBA	Sales Manager, Bettersize Instruments
	Alan F. Rawle, PhD	Emeritus Expert in Particle Sizing and Analysis
	Rama Subba Reddy K, MS	Analytical Expert-ACT Lab-Polymorphism & Nanosizing, Dr. Reddy's Lab. Ltd
12:15 PM – 12:25 PM	***Closing Remarks (virtual attendees)***	
	Robert Lionberger, PhD	Director, ORS, OGD, FDA

12:25 PM – 1:25 PM ***Lunch Break***

Session 8: LD Equipment Demonstrations (In-Person Only)

Similar to Session 3, this hands-on session provides in-person attendees with the opportunity to work directly with LD equipment manufacturers. Participants will rotate through small group demonstrations, gaining practical experience with various LD systems. Vendor representatives will guide attendees through suitable particle size study procedures, highlighting the strengths and considerations of each system. This session aims to deepen participants' understanding of LD technology and its application in complex generic drug development.

1:25 PM –2:10 PM ***Session 8 Demonstrations***

Vendor	Sample
Bettersize	microcrystalline cellulose
HORIBA	cyclosporine
Malvern	cyclosporine
Microtrac	triamcinolone

Session 9: Small Working Group Sessions (In-Person Only)

The final session of the workshop begins with discussions on pre-workshop sample measurements, including cyclosporine ophthalmic emulsions, phytonadione injections, iron sucrose injection, triamcinolone injectable suspensions, and microcrystalline cellulose. Vendors will share challenges encountered during these measurements and propose solutions. Participants will then engage in small group discussions, collaborating on particle size method development, validation, and data analysis.

2:10 PM – 3:10 PM ***Discussion on Measurement of Pre-workshop Samples***
Focus: lessons learned from performing the measurement of five samples

3:10 PM – 3:20 PM ***Coffee Break***

Session 10: Waypoint Exercise (In-Person Only)

The workshop will conclude with a comprehensive summary of key lessons learned and a forward-looking discussion on addressing identified challenges in the near future, setting the stage for continued progress in the field.

3:20 PM – 4:10 PM ***Waypoint Exercise***

4:10 PM – 4:20 PM	***Closing Remarks (in-person attendees)***	
	Darby Kozak, PhD	Deputy Director, OGD, FDA

Appendix of Abbreviations

ACT	Advanced Characterization and Technology
BS	Bachelor of Science
CRCG	Center for Research on Complex Generics
DLS	Dynamic Light Scattering
DPQR	Division of Product Quality and Research
DTP	Division of Therapeutic Performance
FDA	Food and Drug Administration
Inc	Incorporated
KFS	Kfar Saba
Lab	Laboratories
LD	Laser Diffraction
Ltd	Limited
MBA	Master of Business Administration
MEng	Master of Engineering
MS	Master of Science
Mktg	Marketing
NCL	Nanotechnology Characterization Laboratory
OGD	Office of Generic Drugs
OPQ	Office of Pharmaceutical Quality
OPQR	Office of Pharmaceutical Quality Research
ORS	Office of Regulatory Science
PhD	Doctor of Philosophy