

AAPS
ASK the
EXPERTS

STATS
SNAX

ASK THE EXPERTS (AMA)
ABOUT STATS SNAX

BITE-SIZED STATISTICAL CONCEPTS

Stats Snax discusses basic statistical concepts that apply to the pharmaceutical industry using examples from CMC development areas. Designed for non-statisticians, you will learn foundational concepts that CMC statisticians encounter in their daily interactions with clients.

If you've watched the videos and still have questions on the topics covered — e.g., "What is a p-value?" or "How is expiry determined?" — **This is your chance to ask us anything! Hosted by the CMC Statistics Community.**

LEARNING OBJECTIVES: Foundational statistical concepts; How the topic can be used in daily pharmaceutical operations; Proper application of statistical concepts and common misapplication (as appropriate)

Live, 1-hour discussion thread
in the AAPS Community

March 8, 2023 | 11:00 am–12:00 pm ET

Email your questions before the event to
axlers@aaps.org

Watch The Videos on YouTube

Visit the Stats Snax Playlist on **AAPS'**
[YouTube Channel](#)

MEET THE EXPERT PANELISTS

Ben Ahlstrom, MS

Ben Ahlstrom is the Director of Global CMC Statistics at Amgen Inc. and has been with the company for 16 years. Ben oversees a team of statisticians who support large and small molecule product filings, laboratory analytical methods, manufacturing operations, combination product development, and tech transfer. He leads process improvement efforts to standardize analysis approaches to improve quality and efficiency. Ben provides statistical expertise to teams and individuals within operations, and other functions as needed. He has taught numerous classes on statistical data analysis, and design and analysis of experiments, including the use of JMP statistical software. Ben received bachelor's and master's degrees in Statistics from Brigham Young University. He is a past chair of the AAPS CMC Statistics Community, a member of the American Statistical Association, and an *American Society for Quality* Certified Quality Engineer.

Janet Alvarado

Janet Alvarado is currently a team leader in the Center for Mathematical Sciences at Merck, providing global statistical support for Large Molecules in Commercialization and Supply, and delivering statistical training for the Manufacturing Division. Janet is the current Chair of the AAPS CMC Statistics

Community. She holds a bachelor's degree in Chemical Engineering from the Universidad Simon Bolivar (Venezuela) and a master's degree in Statistics from Lehigh University.

Rick Burdick, Ph.D.

Richard K. (Rick) Burdick is an Emeritus Professor of Statistics at Arizona State University, where he has served on the faculty for 29 years. Previously he was Quality Engineering Director for 10 years at Amgen, Inc. He has also served as Principal for Burdick Statistical Consulting LLC in Colorado for seven years. He has been working on statistical issues concerning CMC applications for the past 17 years, and has written over 80 journal articles and four books. Rick is a Fellow of the American Statistical Association, and he served on the USP Statistics Expert Committee from 2010-2020. He received his bachelor's degree in Statistics from the University of Wyoming and his masters and doctorate degrees in Statistics from Texas A&M University.

Laura Pack, MS

Laura Pack currently leads the QC & CMC statistics functions at Rezolute, where she partners with scientists across CMC functions to integrate statistical thinking into everyday decision-making so that the company can advance important medicines through clinical

trials. Laura holds bachelor's degrees in chemistry and biochemistry from the University of Colorado and a master's in applied statistics from Colorado State University. She has served on the AAPS CMC Statistics Community Leadership Team since 2016.

Jonathan Ross

Jonathan Ross is the Associate Director of Manufacturing Sciences and Technology for Upstream Drug Substance at Rezolute Bio and serves as the Member Engagement Manager for the AAPS CMC Statistics Community for AAPS. Mr. Ross previously worked at Seagen, specializing in antibody process development and characterization. Mr. Ross received a bachelor's degree in Biology from Willamette University and is currently pursuing a master's in Applied Statistics from Colorado State University.

Helen Strickland, MS

Helen Strickland is the Senior Statistical Consultant in GSK's Manufacturing Science and Technology organization. With more than 30 years of experience in CMC statistics, Helen provides guidance on the application of statistical methods pertaining to the chemistry, manufacturing and controls for respiratory and HIV products.



Ben Ahlstrom, MS



Janet Alvarado



Rick Burdick, Ph.D.



Laura Pack, MS



Jonathan Ross



Helen Strickland, MS