Moderator:

**Chris Moreton, Ph.D., Partner**  
FinnBrit Consulting  
themoretons@usa.net

Chris graduated from Nottingham University (UK) with a degree in pharmacy. He received his M.Sc in pharmaceutical analysis from the University of Strathclyde (UK) and his Ph.D in Pharmaceutics from the University of Wales College of Cardiff (now Cardiff University). He is a member of several scientific and professional bodies in both the US and Europe. Chris is also on the faculty of Manchester University in the UK on their PIAT distance learning program covering oral solid dosage forms.

He has more than 40 years’ experience in the pharmaceutical industry; mainly as a formulation scientist working in large and small innovator companies, and in generic companies. Chris has also worked in QA, QC and Regulatory Affairs for an excipient and drug delivery company. He has authored papers, articles and book chapters and presented on training courses and at conferences and universities in the US, Europe and Asia in the fields of formulation and excipients.

As a partner at FinnBrit Consulting, Chris provides consulting and advisory services in formulation and process design development and scale up, as well as in aspects of excipients.

Presenters:

**Ajit Narang, Ph.D., Senior Scientist**  
Genentech  
narang.ajit@gene.com

Ajit Narang works for the Small Molecule Pharmaceutical Sciences Department of Genentech, Inc., in South San Francisco, CA responsible for the pharmaceutical development of new chemical entities through preclinical and early clinical stages. He has served as Adjunct Faculty at the Universities of Tennessee, Memphis, TN; University of Phoenix, Phoenix, AZ; University of Nebraska Medical Center, Omaha, NE; University of the Pacific, Stockton, CA; Campbell University, North Carolina; and Western Michigan University, Kalamazoo, MI. He serves as Co-Chair of the Biopharmaceuticals Technical Committee (BTC) of the Pharmaceutical Quality Research Institute (PQRI) in Arlington, VA; a panel member of the International Pharmaceutics Excipient Council (IPEC) committees; Chair of the Formulation Design and Delivery (FDD) section of the American Association of Pharmaceutical Scientists (AAPS); a member of the Systems-based Pharmaceutics (SBP) alliance of the Process Systems Enterprise, Inc. (PSE) in London, UK; and a Scientific Advisor to the Editors of JPharmSci.

He holds over 15 years of pharmaceutical industry experience in the development and commercialization of oral and parenteral dosage forms and drug delivery platforms across preclinical through commercialization stages for both small and large molecule drugs. In addition to Genentech, he has worked for Bristol-Myers Squibb, Co., in New Brunswick, NJ; Ranbaxy Research Labs (currently a subsidiary of Daiichi Sankyo, Japan) in Gurgaon, India; and Morton Grove Pharmaceuticals (currently, Wockhardt USA) in Gurnee, IL. He holds undergraduate Pharmacy degree from the University of Delhi, India and graduate degrees in Pharmaceutics from the Banaras Hindu University, India and the University of Tennessee Health Science Center (UTHSC) in Memphis, TN.

Ajit has contributed to several preclinical, clinical, and commercialized drug products including NDAs, ANDAs, and 505B2s. He is credited with 54 peer-reviewed articles; 22 editorial contributions; 5 books; 10 patent applications; 47 invited talks; and 85 presentations at various scientific meetings. His current research interests are translation from preclinical to clinical and commercial drug product design; incorporation of QbD elements in drug product development; and mechanistic understanding of the role of material properties on product performance.
**Rakhi Shah, Ph.D., Branch Chief in the Office of Pharmaceutical Manufacturing Assessment**
US Food and Drug Administration
Rakhi.Shah@fda.hhs.gov

Dr. Rakhi Shah is a Branch Chief in the Office of Pharmaceutical Manufacturing Assessment (OPMA, formerly known as Office of Process & Facilities) within OPQ/CDER/FDA. Her branch is responsible for conducting holistic assessment of manufacturing for new and generic drug product applications (NDAs, ANDAs, and supplements.) This includes evaluation of processes and also facilities to determine manufacturing readiness; and, making decisions on pre-approval inspections (PAIs) as well as participating in PAIs along with FDA’s Office of Regulatory Affairs (ORA). Additionally, Dr. Shah is also leading OPMA’s efforts of developing a novel risk-based assessment framework for conducting risk based assessments. She also represents the office in various cross-functional initiatives with ORA, Office of Compliance, and other sub-offices within OPQ such as development of New Inspection Protocol Program (NIPP) and Knowledge Aided Structure Assessment (KASA).

Prior to that, Dr. Shah worked in the Office of Generic Drugs (OGD) as a team leader and led a team responsible for evaluating Chemistry and Manufacturing Controls (CMC) information in ANDA applications and supplements including Drug Master Files (DMF). She joined FDA in 2004 and worked in Office of Testing and Research (OTR), where her responsibilities included providing leadership to implement, manage and evaluate product quality research. She received her Ph.D. in Pharmaceutical Sciences from Texas Tech University and holds a Bachelor of Pharmaceutical Sciences and Master in Bioprocess Technology from Mumbai University, India.

**Divyakant Desai, Ph.D., Research Fellow**
Bristol-Myers Squibb Company
divyakant.desai@bms.com

Dr. Divyakant Desai is a Research Fellow in the Bristol-Myers Squibb Company. He obtained his undergraduate degree in pharmacy (B. Pharm.) from University of Bombay, India and his M.S. in Pharmacy from the University of Rhode Island. After getting his Ph. D. from Rutgers in pharmaceutics, he joined Bristol-Myers Squibb. He has been working in the area of oral dosage form for the last 31 years. He was the lead formulator for nine commercial products. He has more than 45 research articles in peer-reviewed journals and many formulation and technology related patents. He won many prestigious awards at Bristol-Myers Squibb for the formulation design of some key commercial products.

**Xavier Pepin, Pharm.D, Ph.D**
AstraZeneca UK
Xavier.pepin@astrazeneca.com

Xavier is a pharmacist (University Paris XI). He has a Ph.D. in granulation technology where he studied powder surface energy and liquid bridges during wet high-shear granulation. He has 25 years experience in the pharmaceutical industry and has occupied several positions from early formulation, clinical and commercial formulation development, industrial transfer, regulatory CMC and biopharmaceutics. He’s worked in biopharmaceutical tools for 10 years in transversal collaboration with scientists from CMC, Clin Pharm & MPK departments, using in vitro, in silico, and in vivo tools to support biopharmaceutical evaluation of drugs along the development value chain and post marketing. He was the co-leader of WP4 in silico tools for the OrBiTo IMI project 2012-2018.

He has 24 publications in the field of powder surface energy, granulation technology and biopharmaceutics.

His hobbies are building homes and furniture, cycling and travelling.