

Q3 Working Group

CHAIR--David W. Osborne, PhD

VICE CHAIR--Bozena Michniak-Kohn, PhD

Origin of the Q3 Working Group

- Norman Richardson organized a one-day workshop entitled “Semi-solid Microstructure” that was held on May 24, 2016 and sponsored by BASF and the Rutgers Center for Dermal Research.
- At a September 28, 2016 dinner at the Renaissance Woodbridge Hotel it was decided to form a Q3 Working Group to further discuss the role of microstructure in the development and approval of topical dermatological products
- On December 9, 2016 the Q3 Working Group Charter and Bylaws were approved by the 16 founding members of the Q3 Working Group

Members of the Q3 Working Group

- From the NDA Side

- Jean-Pierre ETCHEGARAY (Galderma), David Osborne (Arcutis), Gerald PEDRASSI (Galderma), Kevin Warner (Allergan), Gareth Winckle (Galderma) and Ke Wu (Allergan)

- From the ANDA Side

- Padam Bansal (Amneal), Michael Fowler (Teva), Michael Kimball (Teva), Michael Lowenborg (DPT, A Mylan Company) and Stephanie Ng (Acrux)

- From the Vendor/Contract Service Side

- Debra Dow (DDL), Amber Fradkin (KBI), Nigel Langley (BASF), Vijendra Nalamothu (Tergus), Lakshmi Raghaven (Solaris) and Norman Richardson (BASF)

- From Academia

- Bozena Michniak-Kohn (Rutgers) and Narasimha Murthy (University of Mississippi)

Mission of the Q3 Working Group

- The mission of the Q3 Working group is to publish reports on a specific methodology for characterizing a topical product microstructure which includes:
 - A review of relevant literature and statement of current best practices for the technique
 - A detailed listing of required experimental information for future publications or FDA submitted documents
 - A listing of topics that the authors feel need additional basic scientific study and publication prior to establishment of formal quality control procedures/guidelines

Structure of the Q3 Working Group and Chairs of the Q3 Committees

State of Excipients Committee

--Padam Bansal and Norm Richardson

Viscosity/Rheology/Spreadability Committee

--Kevin Warner

Particle/Globule Size and Distribution Committee

--Amber Fradkin and David Osborne

In Vitro Testing Committee

--Lakshmi Raghaven

State of API Committee

--Gareth Winckle and Ke Wu

Q3 Working Group Progress

The Role of Microstructure in Topical Drug Product Development

- Nigel Langley, Bozena Michniak-Kohn and David W. Osborne, editors
- Springer International Publishing AG, AAPS Advances in Pharmaceutical sciences Series.

Contact david.wade.osborne@gmail.com with questions about the Q3 Working Group, Q3 Working Committees, or to obtain a copy of the Q3 Working Group Charter and Bylaws.