

ENGINEERING PHARMACEUTICAL INNOVATION



ISPE Activities

API Community of Practice

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Innovations in Process Technology for Manufacture of APIs and BPCs

ISPE API CoP Introduction

What is a COP? (elevator definition)

A member-driven activity

Connecting & Collecting

- Connecting global members person-to-person
- Collecting relevant information to share

People Tools Knowledge



ISPE API COP -The Vision

Proactively advocate the importance of API in the drug product delivery process with the objectives of providing a forum for members to discuss issues of common interest through:

- Education and training
- Discussion forums
- Regulatory cooperation
- Information dissemination
- Establishment of links to internal and external groups with common interests

ISPE API CoP - Its Value

- Exchange knowledge and experience with industry professionals (over 950 global members)
- Access tools to enhance productivity and keep current on industry trends and developments
- Enhance productivity by contributing to the development of a community Body of Knowledge
- Generate new knowledge and solutions in response to problems and opportunities
- Access to subject matter experts
- Contribute to pragmatic understanding and interpretation of industry regulations
- Promote common language and terminology
- Input to Guides and Standards (living docs)

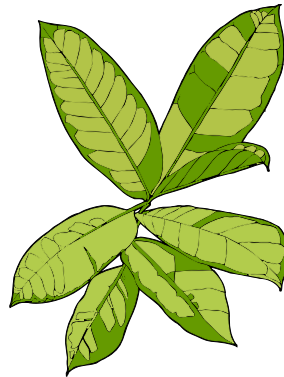
ISPE API CoP - Communication Tools

- ISPE Communities of Practice website – www.ispe.org/cops
 - Membership is free to all.
 - Access to full benefits is free to ISPE members
- CoP E-Letters – www.ispe.org/eLetters
- CoP Meetings and networking events
- Conferences and training

ISPE API CoP Process Technology Group – What the API CoP saw



~2003



now



10-20 years

ISPE API CoP Process Technology Group - Mission

“The API CoP Process Technology subgroup’s mission is to specifically drive *innovations in process technology for manufacture of APIs and BPCs* by the identification of subject matter experts, interaction and partnership with related groups, by support and input to the education program, the promotion / marketing of new innovations in process technology, and input to industry guidelines and best practice documents.”

ISPE API CoP Process Technology Group – Work to date

- Recruited a steering committee for the group,
- *This API Innovations Seminar* –The group inputted into strategy especially themes and subjects, identified speakers, and promoted the event.
- *ASTM standard E55 (07-03) WK9192 Guideline for the application of Continuous processing in the Pharmaceutical Industry* :- Interacting directly with the ASTM group drafting E55 (07-03) WK9192 Guideline for the application of Continuous processing in the Pharmaceutical Industry and to comment on future drafts.

ISPE API CoP Process Technology Group – Steering Committee Members

| | | |
|--------------------------|---------------------------------------|-----------------------------------|
| Prof Paul Sharratt | Prof of Sustainable Processing | Manchester Univ & Britest |
| Prof Andrzej Stankiewicz | Chair EFCE PI Working party | Delft TU |
| Prof Prabir Basu | Pharma Engineering, Britest, NIPTE | Purdue Univ |
| Rick McCabe | Proj Manager innovative projects | Pfizer |
| Prof Bernhardt Trout | Dir. Novartis-MIT Cont Man. Centre | MIT |
| Prof Brian Glennon | Scale-up of chemical and bioprocesses | Dublin |
| Dr Barry Johnson | Equipment development | Alfa Laval |
| Prof Xiong Wei Ni | OFR science and development | Herriott Watt Univ/Nitech |
| Nigel Fletcher | API design | Foster Wheeler UK |
| Dr Peter McDonnell | Implementing cont processing | Genzyme |
| Dr Raf Reintjens | Coordinator for PI | DSM |
| Carol Bye | Sen Dir Head API Quality Operations | Pfizer |
| Ruth Hardy | Technical support pilot plant | Pfizer |
| John Nichols | Cont. Fine Chem Operation, API design | |
| Prof Åke C Rasmuson | Crystallisation in Pharma processes | KTH/Royal Institute of Technology |
| Stan Newberger | Pilot plant, API design | CE & IC |
| Benny Goossen | Chemist development | Janssen |

ISPE API CoP Process Technology Group – Future Plans

1. Develop the API CoP website specific for this group.
2. Solicit membership based upon a draft mission statement
3. Comment on ASTM standard Revision to New Standard E2537 Guide for the Application of Continuous Quality Verification to Pharmaceutical and Biopharmaceutical Manufacturing, WK9935
4. Develop a strategy / roadmap for the promotion of innovative technology.
5. Co-ordinate efforts with the PQLI initiative. Communicate relevant information.
6. Prepare a white paper to be published on ISPE website on relevant regulatory issues. (Utilise existing in-house company information where available)
7. *Information on available innovative technologies and their application* – collate information on the website.

ISPE API CoP Process Technology Group – How you can get involved

- We are looking for interested members to form a wider group
- Promote this innovation in your companies
- Comment on the ASTM documents
- Input to our white papers / roadmap
- Contact Johnjenichols@aol.com or rick.mccabe@pfizer.com