

# Pharmaceutical Engineering: At the Frontier of Drug Substance and Drug Product

*A new ECI Conference*



**May 3-7, 2020**  
**Kloster Irsee**  
**Irsee, Germany**

***Conference Co-Chairs***  
**Daniel Hsieh, Bristol-Myers Squibb (retired)**  
**San Kiang, Porton Pharmatech Co. Ltd.**

### Conference Summary

It is well known that the physical and chemical properties of the DS (API) have major impacts on the formulation and the Drug Product (DP) process. In any dosage form including solid, liquid and semi-solid, the Drug Substance (DS) or Active Pharmaceutical Ingredient (API) goes through a formulation process. This process to make the final drug product serves many purposes, but all with the goal of eventually delivering the active ingredient to the desired sites in the patients' body in the most convenient way and to achieve optimal therapeutic effect.

For most small molecule drugs, the final step in an arduous synthetic sequence is usually the crystallization or precipitation of the DS. This serves as both an isolation as well as purification step. In addition, many particle engineering techniques have been advanced that can tailor the physical and chemical properties of the drug substance during the final step in order to facilitate the design and scaleup of a rugged and reproducible DP processes. From historical and regulatory viewpoints, the blurring of the DS/DP interface while having the potential to offer competitive advantages, there will be regulatory and cultural hurdles that need to be ameliorated. The impact of DS properties on DP performance and the DP processes have attracted wide interest in the industry. However, many engineering issues and mechanistic understanding concerning the DS, the formulation, and their interface still need to be developed and explored. This conference seeks to bring scientists, engineers and regulators working at this critical interface for mutual discussion of current results, future improvement and to identify any technical and regulatory needs that still exist. Participants attending this conference will significantly benefit from learning the innovations from the integration of DS (API) and the formulation of the drug product.

### Program Themes

- **Role of particle engineering**
- **Material science of API/DS and formulation -Impact on drug product performance and process scaleup**
- **Pharmaceutical composite materials**

### Conference Venue

Kloster Irsee (Swabian Conference Centre at Irsee) Nestling in the Alpine Foreland of the Allgäu and located only a few kilometers from walled town of Kaufbeuren, the former Benedictine monastery at Irsee – founded in the 12th century – now houses a modern conference center. Visit the web site for more details: [www.kloster-irsee.de](http://www.kloster-irsee.de)

### Engineering Conferences International

Engineering Conferences International (ECI) is a not-for-profit, global engineering conferences program, originally established in 1962 that provides opportunities for the exploration of problems and issues of concern to engineers and scientists from many disciplines.



**Visit the conference web site for complete details:**  
**[www.engconf.org/20ad](http://www.engconf.org/20ad)**

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## **Abstract Submission now Open**

Submission deadline is January 31, 2020 for long & short oral presentations and poster presentations.

### **Major Sponsors**



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#### **Conference Fees and Registration**

We expect to open registration in November 2019. The estimated conference fee (including registration; single hotel room for nights of May 3, 4, 5 and 6, , and meals from Sunday dinner through Thursday lunch) is US\$1,900, dependent on exchange rates.

**Visit the conference  
web site for a list of  
confirmed speakers.**

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