**FRANK HANAKAM**

*Vice president of process development for Micromet AG in Munich, Germany.*

Who will be most interested in the subject matter of your talk? Start-ups doing drug development and having to decide on “make vs. buy” among GMP production, identifying key drivers and their possible impacts. CMOs might benefit from the presentation as well, as it should bring them a better understanding of the position and requirements of their potential customers.

**What do you expect attendees to “take away” with them?** Better understanding of the complexity as well as possible long-term impact of early decisions among production systems and selection of CMOs. Also, a clearer view on cost structures and uncertainties within production planning, impact of royalties, and their order of magnitude.

**How does the topic fit in to the overall subject of the meeting track?** It answers some of the central basic questions.

**Which presentation(s) are you most looking forward to attending yourself?** Dr. Wolfgang Berthold and Dr. Andrew Sandford are addressing very similar topics and questions as I am. I am also interested in attending Dr. Wolfgang Frieb’s talk on protein formulation.

**What do you think is unique about this conference as a whole?** This conference offers quite an integrated view and covers most relevant aspects among biologicals development.

**What key drivers will you be looking at in your presentation?** Technical feasibility, regulatory compliance, clinical demand, and economic viability. Also, more directly related are selection of an expression system and/or CMO, extrapolation of demand, and COGs (early in development).

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**ANDREW SANFORD**

*Business manager for Dow Biopharmaceuticals Contract Manufacturing Services in Danvers, MA, USA.*

Who will be most interested in the subject matter of your talk? CEOs, CSOs, COOs, process development directors and managers, and investors.

What do you expect attendees to “take away” with them? Investing or accessing advanced technology for performing process development will drive down costs throughout a drug’s lifecycle.

**How does the topic fit into the overall subject matter of the meeting track?** By selecting outsourcing partners who have invested in these advanced technologies, companies can benefit from the rapid development of robust manufacturing programs.

**What do you think is unique about this conference as a whole?** Having an emphasis on economics and how manufacturing costs can be lowered to help support commercialization of more drugs is a very important issue and this conference will address this.

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**BARRY BUCKLAND**

*Vice president of bioprocess research and development at Merck Research Laboratories, USA.*

Who will be most interested in the subject matter of your talk? Anybody involved in development of bioprocess, scale-up, or commercialization of a product. The HPV vaccine that I’ll be talking about is in a very late stage of development, and we’re working toward commercialization and development, and we’ll be filing this summer. Also, generally people interested in vaccines and tech transfer.

**What do you expect attendees to “take away” with them?** I think excitement about the product. Secondly, some of the unique challenges working with yeast fermentation and working with virus-like particles as opposed to cell culture and proteins. It will be informative in terms of the unique analytics and working with the product. Vaccines, which have traditionally been developed in a different way, are now being developed like biotech products.

**How does the topic fit into the overall subject matter of the meeting track?** We’re going through the whole development cycle. It’s also linking scale-up to the clinical outcome.
What do you think is unique about the conference as a whole? The general theme of bioprocess development is of great interest. My group is focused on bioprocess development, so we’re very interested in the conference. At our company, the biotech part is relatively small, but it’s rapidly growing.

What has reenergized the vaccine industry in recent years? The biggest drive is unmet medical needs, and so there are certain diseases where vaccines can to contribute. It seems that cervical cancer is one of these areas. Controlling HPV infection can do that. Then there’s opportunities for different cancer vaccines. As understanding about biology advances there’s a lot of new opportunities emerging.

How many vaccines does Merck have in its development pipeline? In late-stage development we have four: cervical cancer, shingles, rotavirus, and a combination vaccine for MMR and varicella based on live virus products.

Is the filing of your HPV vaccine in 2005 going to be in the United States, Europe, or elsewhere? It will be a market application in both the US and Europe. All four vaccines in late-stage development are slated for filing in 2005.

JOSEPH PHILLIPS

Senior director of analytical sciences at Amgen in Thousand Oaks, CA, USA.

Who will be most interested in the subject matter of your talk? This talk will be of interest to bioprocess scientists and engineers engaged in bioprocess development as well as bioanalytical scientists engaged in developing methods to support monitoring bioprocess performance optimization and scale-up. Additionally, this will be interesting to QC analysts responsible for supporting manufacturing of clinical supplies and release of final purified bulk drug.

What do you expect them to “take away” with them? This talk proposes leveraging of similarities and uniqueness of monoclonal antibodies in a method development strategy to allow minimal resource requirements to generate fit-for-purpose analytical methods during the early phase of bioprocess development.

How does the topic fit into the overall subject matter of the meeting track? Platform strategy for analytical technologies in early drug development fits into the vision of getting drug candidates into clinical trials in the shortest time possible with minimum resource use in process optimization, scale-up, and developing analytical controls.

Which presentations are you most looking forward to attending yourself? Those presentations addressing speed to first-in-human clinical trials.

What do you think is unique about this conference as a whole? Understanding the challenges that we face as an industry that is operating on the cutting edge of biotechnology.

How do you define the term “platform technologies”? The ultimate in platform technologies is a set of equipment, procedures, and operating conditions that are immediately applicable and require no further optimization for successful manufacturing, characterization, and release testing of any new drug candidate molecules within a class (e.g., monoclonal antibodies).

Does it involve more automation of tasks? It is not so much automation of unit operations, but more the ease of fitting existing “platform” unit operations into the manufacture, characterization, and testing of new entities.

Is it only appropriate to early development? The immediate interest is in early development where the speed to clinic is key to drug development success.

Will it have further application down the line as well? Through evolution of platform technologies for particular classes of bioproducts, it is hoped that we can drive more consistency in quality and reduce resources for fitting processes into existing manufacturing plants.

Are PATs used more by US or European companies? The application of existing technologies in the PAT setting for bioproduct manufacturing is in its infancy in both the United States and Europe. Building final product quality into continuous process monitoring and feedback is widely accepted.

Will their increased implementation require more statistical skills on the part of people involved in bioprocessing? The skills in statistics — in particular chemometrics — as applied to PAT will be more integral in the development of technologies and their applications, as opposed to routine uses.

Do you see a lot of work traditionally done by analytical laboratories being automated by PATs in the future? PAT is not so much automation of current laboratory tests; it is more changing how in-process monitoring and controls are used, with feedback built into the process to make changes to unit operations in a continuous real-time manner to deliver final product of the desired quality.


