biotech stage
New opportunities at every step

Global Biologics India April 24-25, 2024

Panel Discussion- Day 1- Cell and Gene Therapy

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Moderator: Shawn Smith

Panel Members:

1. BN Manohar**,** Ph,D. **CEO- Stempeutics**, India
2. Ivone Bruno**,** Ph,D., **VP Preclinical affairs** and Process Development **CytoImmune**, USA
3. Vishwas Kaveeshwar, Ph.D., **Incharge/Asst. Professor**, SDM University, India
4. Dinseh Kundu, MBBS, MBA, **Co-Founder and Director, East Ocyon Bio,** India
5. Rushikesh Patil, Ph.D., **Senior Scientist, ImmunoACT**, India
6. Rajesh Kolli, Ph,D., **Head Cell and Gene Therapies, Reliance**, India
7. Ravindra Patel, **Founder and Chief Technical officer, OmniBRx**, India

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Panel Discussion- Day 1- Cell and Gene Therapy

Topics Discussed

- **Starting in the domain of scientific development and innovative technologies, are you seeing more or less trending of collaborations - from consultative guidance to outsourced lab activities - between academia and industry? Publish vs Patent? Any personal examples of successful interactions and lessons learned?**

- **As new and improved technologies are considered by industry, are the 'rules' for formal validation changing [becoming more or less stringent]? Do you find that the challenges or barriers to successfully implementing process changes or scale-up protocols to be driven more by 'technology', 'cost', or effort to meet 'regulatory' requirements**

- **Achieving commercial success will mean satisfying regulatory requirements of the targeted regions for commercial launch, but it will also mean having the logistical means to deliver the product and a therapeutic cost basis affordable to prospective patients; how much will more standardized [or 'platform'] processing contribute to both ease of regulatory pathway and cost containment (at commercial scale)? Is automation possible?**

- **Many conference attendees are more familiar with biotherapeutic proteins, notably MAbs (original or biosimilar): can you briefly highlight some principal differences between gaining regulatory approval for Cell & Gene Therapy vs biosimilars?**

- **From clinic to market: once the process is defined, what are the most critical aspects of successfully engaging in clinical activities leading towards market approval?**

- **Have you considered using outsourced processing partners [CDMO]? how much does 'location' vs 'reputation/expertise' vs 'cost' matter?**

- **What key steps are required of Indian biotech companies to successfully compete globally?**

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Panel Discussion- Day 2- MABs and Proteins

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Panel Discussion- Day 2- MABs and Proteins

Moderator: Shawn Smith

Panel Members:

1. Sanjeev Gupta, Ph,D. **Sr. VP and Head-Biosimilars. IPCA**, India
2. Venkata Ramana, Ph.D. **Chief Scientific officer, Reliance** Life Sciences, India
3. Praveen Reddy, Ph.D., **Deputy General Manager, Global Regulatory Affairs, Lupin**, India
4. Satish Makkina, **General Manager Biologics, Procell Biologics**, India
5. Ankur Bhatnagar, **Head Process Sciences, Biocon**, India

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Panel Discussion- Day 2- MABs and Proteins

Topics Discussed

1) Scientific development arises from both academia and industry, and where academia once lived under the banner or 'publish or perish', more consideration is now given to 'patent or partner' in that intellectual property has become a key element of biotechnology's maturation and the manner in which institutions of higher education interact with industry

2) How challenging is it to implement a non-CHO mammalian line for biosimilar MAb production? qualification/validation, characterization, genetic stability, ability to confer post-translational modifications, etc -- do technical challenges combined with the 'comfort' of historical precedent hinder advancement?

3) Alternatives to mammalian cells: from insect cells to yeast to prokaryotes: can secondary- or downstream molecular modifications enable lower-cost fermentation models

4) Process technology and IP: concentrated fed batch, unique platform systems, 'turn-key' single-use bioreactors - when vendors supply a solution where only they possess the 'key' ... does 'inbound' IP represent a barrier or opportunity to engage?

5) Upscale [50L to 2000L+] to out-scale ['tank farms' of multiple 'smaller' units], outsourcing to obtain scale [larger CMO capacity] vs greenfield build-outs (keeping activities in house): what approaches to 'generating more volume of drug product' do you prefer and why?

6)When building or expanding a bioproduction facility, do you favor single-use/modular designs or more traditional configurations? how does 'implementing change' [new/next-gen processes] or contending with multiple products manufacturing impact these considerations? while also incorporating scale/capacity and location/logistics, the particular question here pertains to proactive design of facilities with regard to implementing ongoing technology evolution and its impact on regulatory status {i.e., the concept of 'flexible discipline' or 'disciplined flexibility'}

7) Commercialization of biosimilars, from patent expiration tracking to targeting regions for early adoption, requires both market intel vigilance and long-term project management; 'milestones' [or 'gates', should you employ a stage-gating process] contain go/no-go decisions or the need for further development: considering the convergence of time [speed to market], regulatory approval [where 'change' to processing can add validation time], and cost, do you have general thoughts around how and when implementing project changes are acceptable vs carrying on as is (with a perhaps suboptimal yet viable process)?