Cell Culture Bioprocess Learnings: Past successes and future challenges

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Cell Culture Bioprocess Learnings - ten thought provoking views

Günter Jagschies, GE Healthcare Life Sciences
BioProcess Capability Days, Japan

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Please contact me at guenter.jagschies@ge.com in order to request a complete copy of my keynote presentation at CCE in Tampa
#1 - Health challenge transition

**Nigeria**

**Juvenile**
Dominating communicable disease

Hygiene, access to care; high newborn and maternal mortality

Unsafe life conditions

**India**

**Young**

Still significant communicable disease burden

Sharply growing noncommunicable disease: CVD, cancer, diabetes, chronic respiratory disease

Unsafe life conditions


*Demographic transition, Source CIA, The World Factbook 2016, blue = male, red = female*

Increase of >65 population by 2.3 bn (until 2100) in Asia and Africa

#4 - Beyond antibodies
Time to simplify and to integrate

Innovations in therapeutic molecules

- Antibody drug conjugates
- Bi-specific mAbs
- Fragments
- Nucleic acids
- Scaffolds
- Gene therapies
- Cell therapies
- mRNA

Biomanufacturing toolbox

Flexible unit operations, multi-molecule capable
HTPD*, QbD*, PAT*
Integration
Continuous processing
Automation, data integration, digitalization

Facility design

Simplification
Single-use technology
Minimal foot print
Right-sized, scale out
Minimal piping
smaller & less tanks
Matching demand increase or new market entry

Modularity, wheel in-wheel out equipment
SUT* standards
E&L* service standards

Digitalization
Less complex equipment, no bespoke solutions
In-and at-line analytics

*E&L = extractables and leachables, HTPD = high-throughput process development, PAT = process analytics technology, QbD = quality by design, SUT = single-use technologies

Günter Jagschies - BioProcess Capability Days 2018
Cell line development (CLD)
- Reduction of CLD time from 40 weeks (traditional) to 10 weeks
- Less screening: more projects, more time for difficult to express proteins
- Product quality, not just titer !!!

Cell culture, batch
- Titers reach or exceed 10 g/L
- Advanced approaches to boost viable cell density
- Fine tuning "nutrition"
- Time compression for inoculation train and production reactor

Cell culture, perfusion
- Foot print reduction ~50% (5-10 fold vol reduction)
- Elevated volumetric productivity (3-5 g/L/day) and reduced perfusion rate (0.2-0.5 RV/day)
- Mitigate perceived or real business risks via simplification (e.g., iSKID)
#10 - Disease challenges far from solved
Unlikely for any company to address these challenges alone!

Lose against antimicrobial resistance?
Win over cancer?

Biotherapeutics for the most complex diseases we know, such as cancer or diseases of the nervous system, are still in the earlier phases of their efficacy and potency related “learning curves.” Consequently, additional generations of biotherapeutics will have to be developed before one may hope for victory over those diseases or even for regularly bringing patients back to a status where life with the disease is long-term manageable.
Biopharmaceutical Processing (just published)
Günter Jagschies, Eva Lindskog, Parrish Galliher and Karol Łącki

58 chapters covering
- Disease priorities
- Biopharma business
- Process capabilities & designs
- Principles & Methods
- Equipment & Facilities
- Analytics, Quality, CMC
- Industry case studies
- Economics of bioprocessing

100 authors, 1.200 pages
