BIOLOGICS I:

- DISPOSABLE SENSORS AND DISPOSABLE PROCESSING EQUIPMENT

- AT-LINE/IN-LINE ANALYTICS

Victor Saucedo

Genentech, Inc.

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Disposable Equipment

Wave Biorectors

Single Use Biorectors

Table 1 Factors driving the growth of single-use systems in biopharmaceutical manufacturing

Market factors	Advantages	Current limitations
Emphasis on production costs	Reduced capital costs for plant construction and commissioning	Leachables and extractables
Flexible, multiproduct manufacturing facilities	Reduced risk for product cross-contamination in a multiproduct facility	Prior investment in fixed equipment
Biosimilars	Rapid changeover	Scales limited by current 2000 liter cell culture bioreactor capacity
Multiple, smaller manufacturing plants colocated with markets	Lower utility costs due to reduced need for SIP	Limited number of vendors
Increasing number of low-volume biopharmaceutical products	Reduced need for cleaning validation	High cost of disposables
		Lack of universal standards for vendors
		Solid waste disposal

Mixing systems, bioreactors, and membrane adsorbers
The growth rate in each sector is 20-30% (fully single use or hybrid)

Single-use disposable technologies for biopharmaceutical manufacturing, Trends in Biotechnology, Volume 31, Issue 3, 147-154, 26 November 2012

Example

- Truly disposable
- Several challenges
  - Range
  - Integration
  - Compatibility
- Key Successes
  - Collaboration
  - Continuous Research
- Work in Progress

Disposable Sensors I

1. Who is using disposable sensors? Most recent success stories?
2. What are the main disposable sensor challenges and how have they been addressed?
3. What are the main disposable sensor needs?
4. What are the main requirements?
5. Is industry adapting to the technology? What else needs to be done?
6. What are the “dream” disposable sensors?

Disposable Sensors II

1. Value using disposable sensors with SS equipment? Reduction in bioburden? Cross-contamination?

2. Understanding reliability of sensors (impact of gamma irradiation). Are data provided by supplier sufficient?

3. Influencing suppliers on selection of MOC keeping process conditions in mind. Collaboration and consumer survey.

4. What can industry do to improve the development and acceptability of new disposable sensors?

At-line/In-line Analytics

1. What are current needs? Latest success stories?
2. Improving existing or new platforms?
3. What are the main challenges for at-line/inline analytics?
4. Where should the analytics industry be in 5-10 years?
5. What can industry do to improve the development of new analytics?

Disposable Equipment

1. Who is using disposable equipment? Latest success stories?
2. What are the main disposable equipment needs?
3. What are the main disposable equipment challenges?
4. What are the main requirements?
5. What can industry do to improve the development and acceptability of new disposable equipment? Standards? How to dispose?

Disposable Equipment

1. Qualification requirements for Single use vs SS
2. Is closed processing a requirement?
3. Scalability (requires a separate hardware for different scales, e.g. 10, 50L, 200L) – how do we increase flexibility
4. Automation Needs
5. Is it more complex?
6. Needs of single use in Drug product
7. DS vs DP requirements