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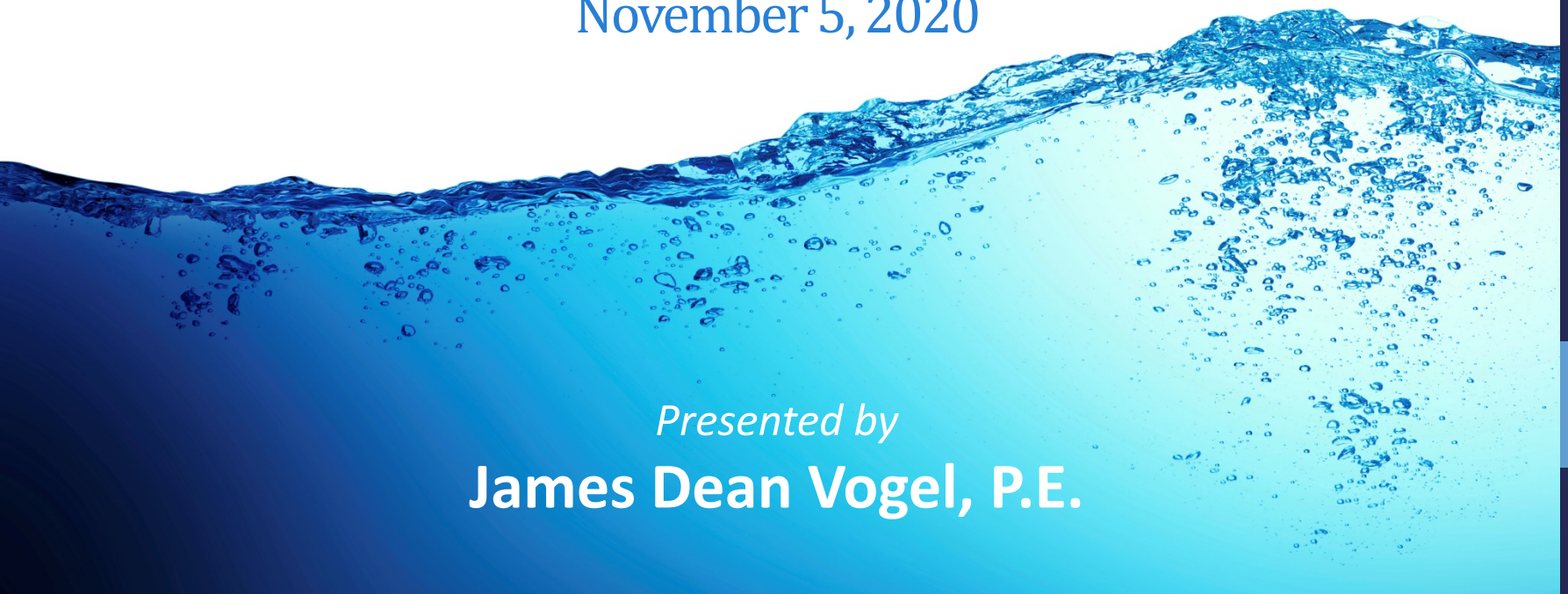
BPSA
Bio-Process Systems Alliance
Advancing Single-Use Worldwide

Guide to Single-Use Training Series: Part 1

Biopharmaceutical Manufacturing & SUT: General Review of the Biopharmaceutical Processes

November 5, 2020



Presented by

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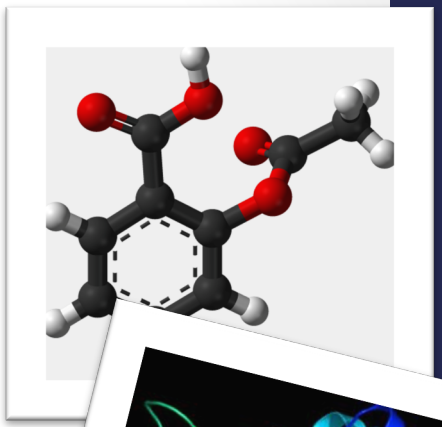
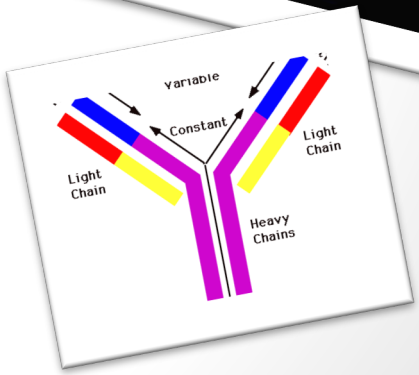
What's the difference?

- **Conventional Drugs**
  - Small Molecules (hundreds-thousands molecular weight)
  - Usually chemical synthesized
  - Also known as Active Pharmaceutical Ingredients (APIs)
- **Biological Drugs (Biologics)**
  - Large Molecules (millions of molecular weight)
  - Protein-based
  - Virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention, treatment or cure of diseases or injuries of man.





BioPharmaceuticals Mature

- Big Business/$Billions
- Emerging Markets (China, Russia, Brazil, India)
- Efficiencies/Cost of Goods
- Patents /BioSimilars
- Individualized therapies (Cell and Gene)

What is the industry doing to meet these changes?

Fermentation/Cell Culture

- Grow cells
- Protect
- Feed
- Remove waste
- Scale up to useful volumes
- Cells manufacture product

MAKE the cells happy so they will reproduce and then make the product!!

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What properties can you exploit in a separation?

Downstream products can be purified based on one or several of the following in combination:

- Size/Shape
- Electrostatic charge
- Biospecific recognition
- Solubility
- Hydration state
- Hydrophobicity
- Metal ions/co-factors
- Secondary modifications

The little c in cGMP

(current)

Process:

- Interpreting the desired outcome of the regulations
- Assess current practices to assure outcome or integrate new practices
- Rewrite procedures and re-train personnel

This is why we are here!

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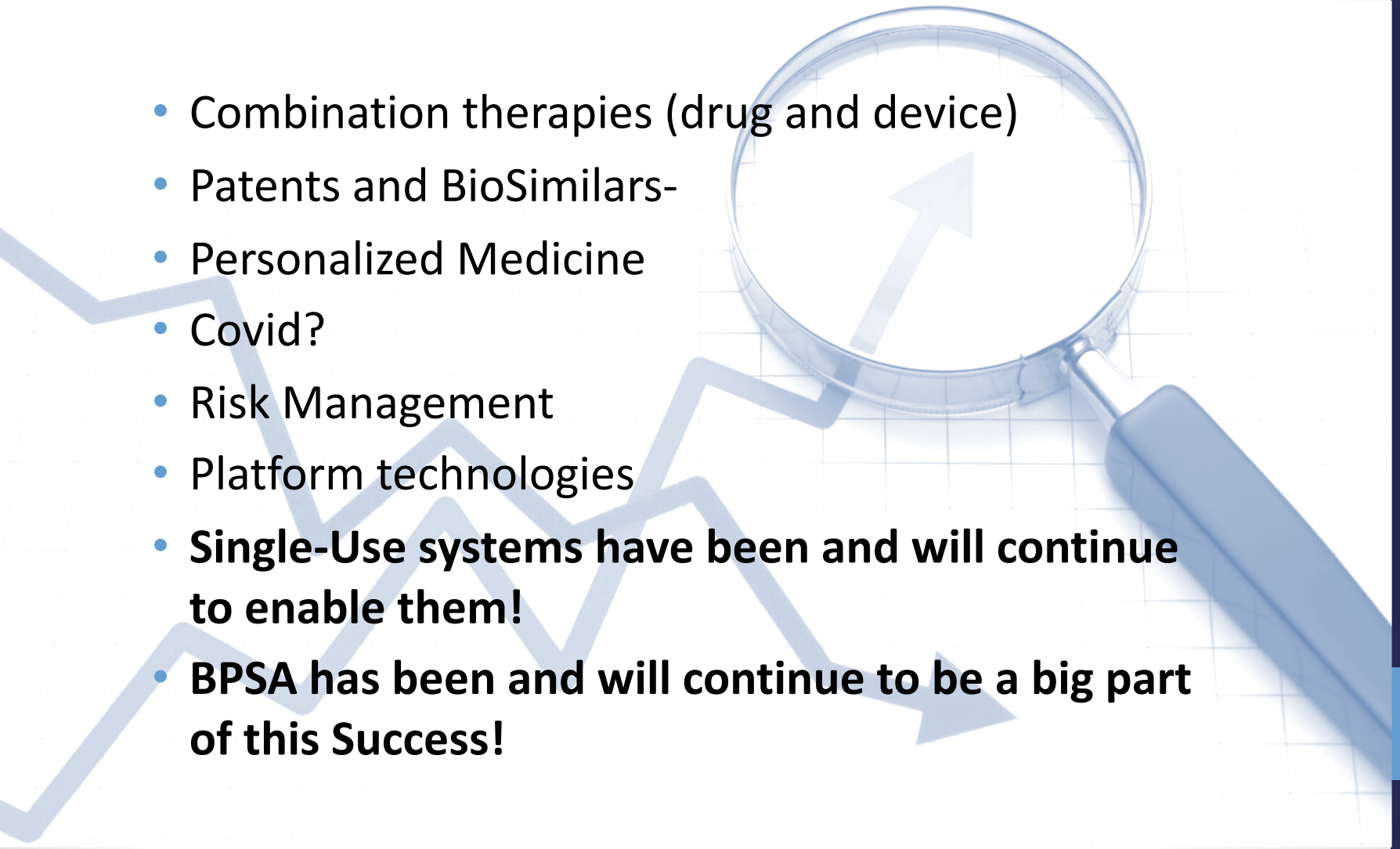
Biopharmaceutical Regulations

- Regulations will continue to harmonize
- Regulations will change based on fundamental changes in medicine
  - Better science
  - Streamlined
- Regardless of regulations, drug development and manufacturing should be
    - Science based
    - Manage risk
    - Be in control
    - Protect the patient

Current Biopharmaceutical Trends



- Combination therapies (drug and device)
- Patents and BioSimilars-
- Personalized Medicine
- Covid?
- Risk Management
- Platform technologies
- **Single-Use systems have been and will continue to enable them!**
- **BPSA has been and will continue to be a big part of this Success!**

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end users

Our goal is to help our clients make better drugs

suppliers

www.bioprocessinstitute.com