Bioprocessing Technology Institute
BTI

Biologics Pharma Innovation Programme Singapore (BioPIPS)

Grant Call for (1) Sensing and Modelling and (2) Sustainability

CREATING GROWTH, ENHANCING LIVES

Content

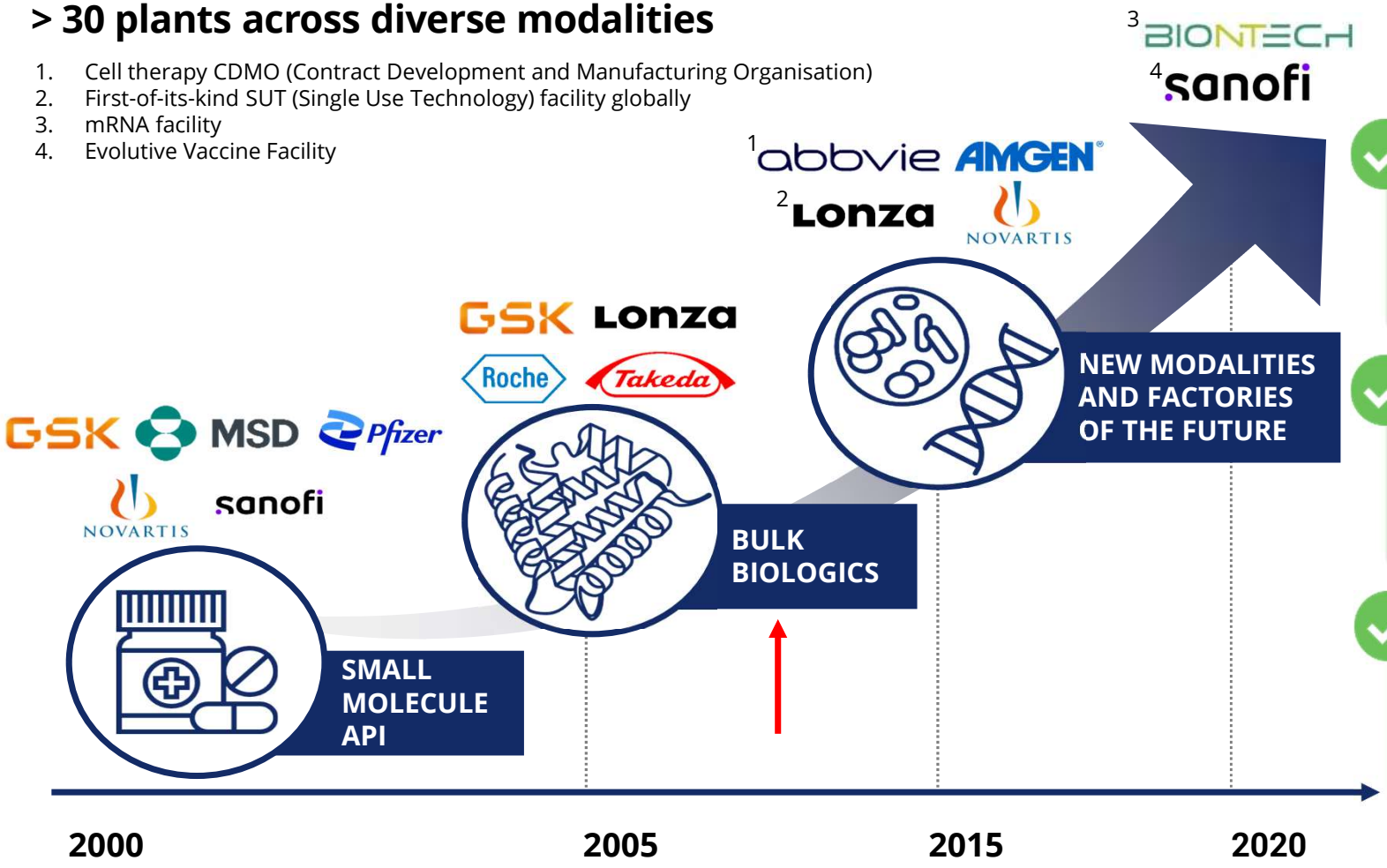
1. Pharmaceutical Manufacturing in Singapore
2. Introduction to BioPIPS
3. Sensing and Modelling
4. Sustainability
5. Administrative Notes

CREATING GROWTH, ENHANCING LIVES

Pharmaceutical Manufacturing in Singapore

> 30 plants across diverse modalities

1. Cell therapy CDMO (Contract Development and Manufacturing Organisation)
2. First-of-its-kind SUT (Single Use Technology) facility globally
3. mRNA facility
4. Evolutive Vaccine Facility



2020 BIOPHARMA SECTOR PERFORMANCE

Manufacturing Output

S$15.7B

Value Added

S$8.8B

Employment

>8,900 employees

CREATING GROWTH, ENHANCING LIVES

Multi-Pronged Strategy

Helping companies meet new needs and enhancing Singapore's competitiveness

Technology

Driving productivity, encouraging introduction of new products and enabling manufacturing of new modalities

Strengthening existing manufacturing base via process and technology innovations

Preposition Singapore for manufacturing of new therapeutic modalities

Manpower

Growing and strengthening our base of manufacturing talent

Preparing an industry-ready workforce

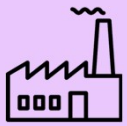
Equipping workers with the right skills through local and overseas on-the-job training

Enabling workers to build a career across various levels of experience

Infrastructure

Providing industry with innovative capacity solutions

Increasing outsourced development and manufacturing capacity in Singapore



Providing flexible infrastructure options

Supplier Ecosystem

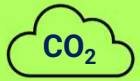
Diversifying the supplier and supply chain ecosystem

Identifying critical supply gaps in the supplier ecosystem

Encouraging new suppliers who can meet these needs to set up in Singapore

Sustainability

Supporting sustainable growth and operations in Singapore



Advancing decarbonisation pathways for industry

Expanding capabilities in circular economy

Growing an enabling environment to support sustainability needs

CREATING GROWTH, ENHANCING LIVES

Technology Innovation and Development

Accelerating manufacturing technology development and implementation in Singapore sites

Biopharmaceutical Deep Dive endorsed by MTC EXCO on 7 September 2022

LEVERAGING ADVANCED MANUFACTURING TECHNOLOGIES

Strengthen the Existing Manufacturing Base through Process Innovations

SMALL MOLECULES

Pharma Innovation Programme Singapore (PIPS)

Active Ingredient to Product Interface

Agile Factory of the Future

Manufacturing Technology Platforms

Plant Operations

Tools for Accelerated Process Development and Process Technologies

GSK MSD Pfizer syngenta

BIOLOGICS

Biologics Pharma Innovation Programme Singapore (BioPIPS)

Sensing and Modelling

Sustainability

Compliant Agility

BIONTECH GSK sanofi

Preposition Singapore for Manufacturing of New Therapeutic Modalities

CELL THERAPY

Singapore Cell Therapy Advanced Manufacturing Programme (STAMP)

Autologous T-cell Therapy Manufacturing

Mesenchymal Stem Cell Manufacturing

Critical Analytics for Manufacturing Personalised Medicine Programme

GENE THERAPY

Nucleic Acid Therapeutics Initiative (NATi)

Smarter Drug Design

Process Optimisation

Targeted Delivery

NATi

CREATING GROWTH, ENHANCING LIVES

About BioPIPS

Objectives

Leverage public sector R&D capabilities to –

- ***Address problem statements*** from local biologics manufacturing facilities
- ***Enhance manufacturing productivity and operational efficiency***

Desired Outcomes

Transform the existing biologics manufacturing operations in Singapore so that the manufacturing sites are –

- ***Best-in-class*** within their respective manufacturing network
- Well positioned for the ***introduction of new products and novel manufacturing technologies***

Case for BioPIPS

Leverage strong foundation to launch BioPIPS

- ***Synergies*** in operations, resources, learning and collaboration of technologies with PIPS
- ***Interest*** from companies to form the consortium

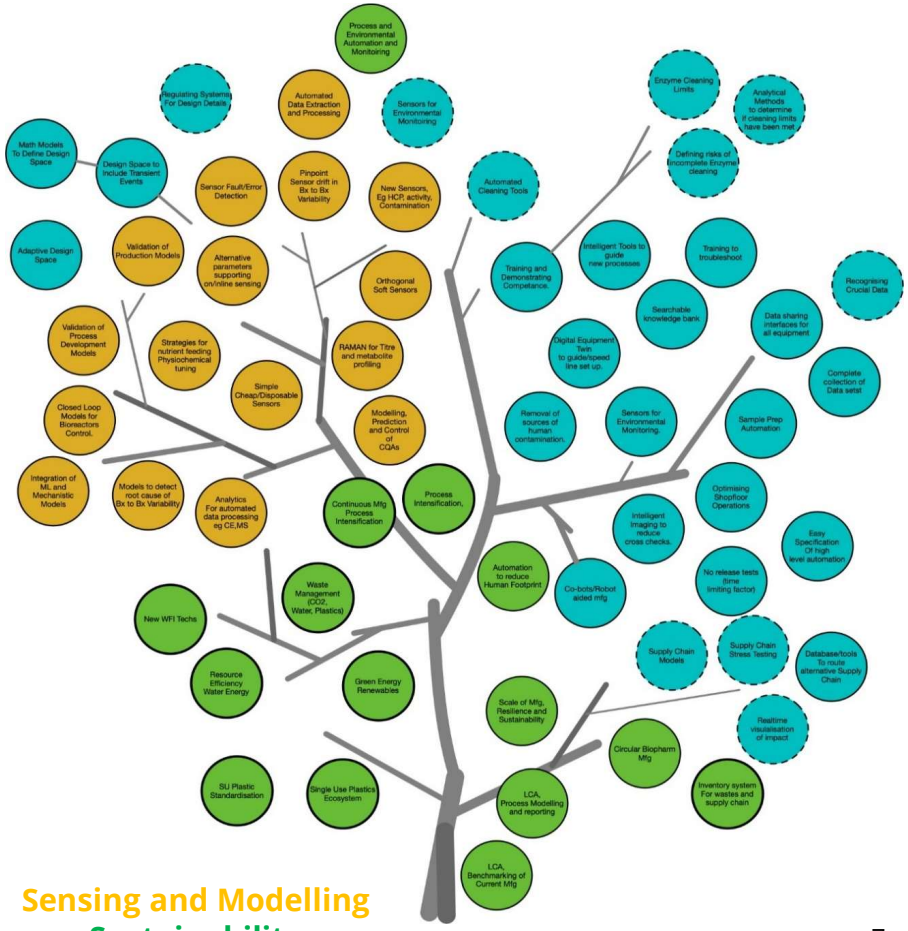
Definition of Workstreams through Industry Roundtable Discussions

These workstreams are generated through discussion to address the dual challenge of (1) Directing research to improve productivity of existing manufacturing capabilities and (2) Exploring solutions to fundamentally improve the long-term resilience and sustainability of vaccines and biopharmaceuticals manufacture.

Sensing and Modelling – focuses on generating fast, in-process and automated workflows to translate process performance into actionable knowledge. Specifically, the aim is to improve the accuracy and robustness of sensing technologies and facilitate the incorporation of AI and modelling approaches into manufacturing processes to enable quicker and more effective product and process control.

Sustainability – focuses on technologies to achieve sustainability targets. These include using models to identify bottlenecks in manufacturing and supply chain, exploring impact of new technologies to reduce resource utilisation and re-thinking the expanded utility of single-use equipment through the lens of materials science and circular economy considerations.

Compliant Agility – focuses on removing manual tasks to achieve greater productivity in the manufacturing facilities while maintaining compliance status by using solutions, e.g. robotics and advanced analytics.



Sensing and Modelling
Sustainability
Compliant Agility

Sensing and Modelling

Sensing and Modelling

Batches of biopharmaceuticals are expensive with tight manufacturing regulations. Current manufacturing processes **follow exact recipes** to **control quality and yield of products**. The ability to control biological processes is constrained by the capability to monitor, analyse and combine data to gain insight.

In the **Sensing and Modelling** workstream, the aim is to develop and validate in-process, automated analytical workflows to ensure **accurate monitoring** of **process parameters and product quality** which will in turn **facilitate adaptive control strategies** in the form of real- or near real-time corrections to manufacturing unit operations. These objectives will be achieved through **improvement of sensor technologies** and the **incorporation of modelling techniques** to predict outcomes and enact changes to manufacturing conditions.

CREATING GROWTH, ENHANCING LIVES

Real-time Bioburden and Endotoxin Detection – Sensors and Modelling Approach

Bioburden (BB) is the number of harmful microorganisms and endotoxins are specific lipopolysaccharides (LPS) which cause harmful effects when released from gram negative bacteria. *Current contamination tests, routinely assessed throughout biomanufacturing process, take up to 6 – 7 days.* ***This turn around is a major bottleneck*** *in cleaning validation workflows.*

The project can involve one or more sensors, e.g. spectroscopic, biochemical, biophysical, etc in combination with computational modelling. The project will involve a feasibility study to identify suitable sensor technologies for fast detection of BB and LPS. It will have two parts:

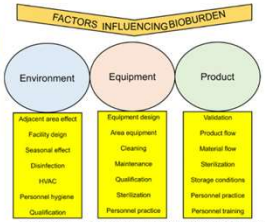
1. *Develop a POC real-time/online system to determine if BB/LPS has exceeded safe limits (POC on cleaning validation samples)*
2. *Validate a list of technologies in Part 1 above showing robust and adaptable solutions which can meet the same or better benchmark than current gold standard kits*

Current solutions

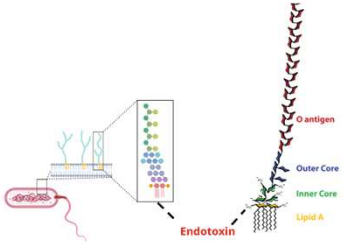
- At-line detection kits currently available
- Reagents are inside kits and cannot do online as it will involve interacting with the product
- Any new method should be compared to these solutions (sensitivity, accuracy)

charles river
Lonza
MERCK


Images from sigmaaldrich

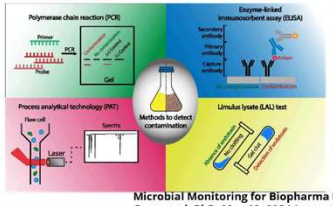


Tim Sandle, in Pharmaceutical Microbiology, 2016



Bioburden	Endotoxin
The number of microorganisms found in a sample	Specific toxin released by microorganisms
Refers to all harmful microorganisms	Specifically refers to lipopolysaccharide (LPS) of gram neg bacteria
Can be quantitatively expressed as colony forming units	More difficult to quantitate (expressed as EU/mL)

Regulatory requirements: ISO 11737-1, ISO 11737-2, ISO 11137-2, USP 61 & ISO 11737-2



Microbial Monitoring for Biopharma Manufacturing, Aron Gyorgypal, PhD, May 10, 2024 (www.technologynetworks.com)

Development of Technologies for Accelerating Contamination Monitoring

There is uncertainty regarding the operationalisation of a real-time sensor system for endotoxin and bioburden detection, particularly when working with complex and variable manufacturing conditions. In a production environment, decisions need to be made quickly and easily by operators. Currently, bioburden and endotoxin testing are done offline/at-line at all stages of a pipeline. A crucial stage for detection is during cleaning validation purposes where too much time is required to obtain results. This delay also prevents real-time decision-making which can lead to potential contamination risks to products and inefficiencies in batch management.

Problem Statement 1 – Online/Real-time Bioburden and Endotoxin Detection

There is a need for a comprehensive feasibility assessment and subsequently a proof-of-concept study to assess the operational effectiveness and sensitivity of sensing technologies (new sensor or combination of existing sensors) for bioburden and endotoxin detection in cleaning validation samples. The study must include an evaluation of matrix effects and background interference to determine how these factors influence the technology's performance in real-world settings. In addition, cataloguing existing sensing technologies and new sensors is vital.

Development of Technologies for Accelerating Contamination Monitoring

Scope

1. A comprehensive literature review to understand existing methods and technologies, identify gaps and define regulatory insight, e.g. compendial methods from the United States Pharmacopeia (USP) and European Pharmacopeia
2. Non-invasive detection method/technology to detect if endotoxin and/or bioburden are outside safe limits
3. The proposed method/technology should refer to the compendium methods for specifications on safe limits. For instance, the allowable bioburden for sterile drug products is <10 CFU/100 mL (colony forming units) and the endotoxin limit is typically <0.5 EU/mL (endotoxin units per millilitre).
4. Start with Water-for-Injection (WFI) as a matrix to assess the feasibility of the method for cleaning validation. Following the successful feasibility study, collaborate with stakeholders to identify the most appropriate representative bioprocessing samples for method development to ensure that they reflect typical process conditions.
5. Assess whether the method/technology is sensitive to background or matrix effects while acknowledging variations in matrix composition

Desired Outcome

1. Develop a catalogue of potential online methods for cleaning validation samples, e.g. sensors, models to detect for bioburden and/or endotoxin which is compatible with defined safe limits as described in compendial methods (10 CFU/100 mL for bioburden and <0.5 EU/mL for endotoxin)
2. The solution is evaluated and verified for compliance with applicable regulatory requirements, i.e. solution should be assessed for comparability with current compendial methods

Development of Technologies for Accelerating Contamination Monitoring

Problem Statement 2 – Ensure Certainty on Accuracy and Sensitivity of a Model for Cleaning Validation

While solutions combining sensors and models for endotoxin and bioburden detection have potential, there are challenges in operationalising them effectively for cleaning validation. The output can be either difficult to interpret or not sufficiently accurate leading to lack of implementation of such solutions. Consequently, traditional offline testing methods still dominate the process.

Scope

1. Develop and implement a soft sensor-based/machine learning solution which uses real-time sensor data to predict contamination levels to enable immediate classification, such as **'safe or unsafe' for use in cleaning validation**
2. The solution should be designed to minimise batch failures by providing quick and accurate predictions which help operators make informed decisions during critical stages
3. The solution's sensitivity and accuracy should be **validated** in a WFI matrix by comparing to offline/at-line gold standards, such as https://www.criver.com/products-services/qc-microbial-solutions/endotoxin-testing/kinetic-chromogenic-cartridge-technology/lal-cartridges?region=3656 and https://bioscience.lonza.com/lonza_bs/SG/en/winkqcl-endotoxin-detection-and-analysis-software.

CREATING GROWTH, ENHANCING LIVES

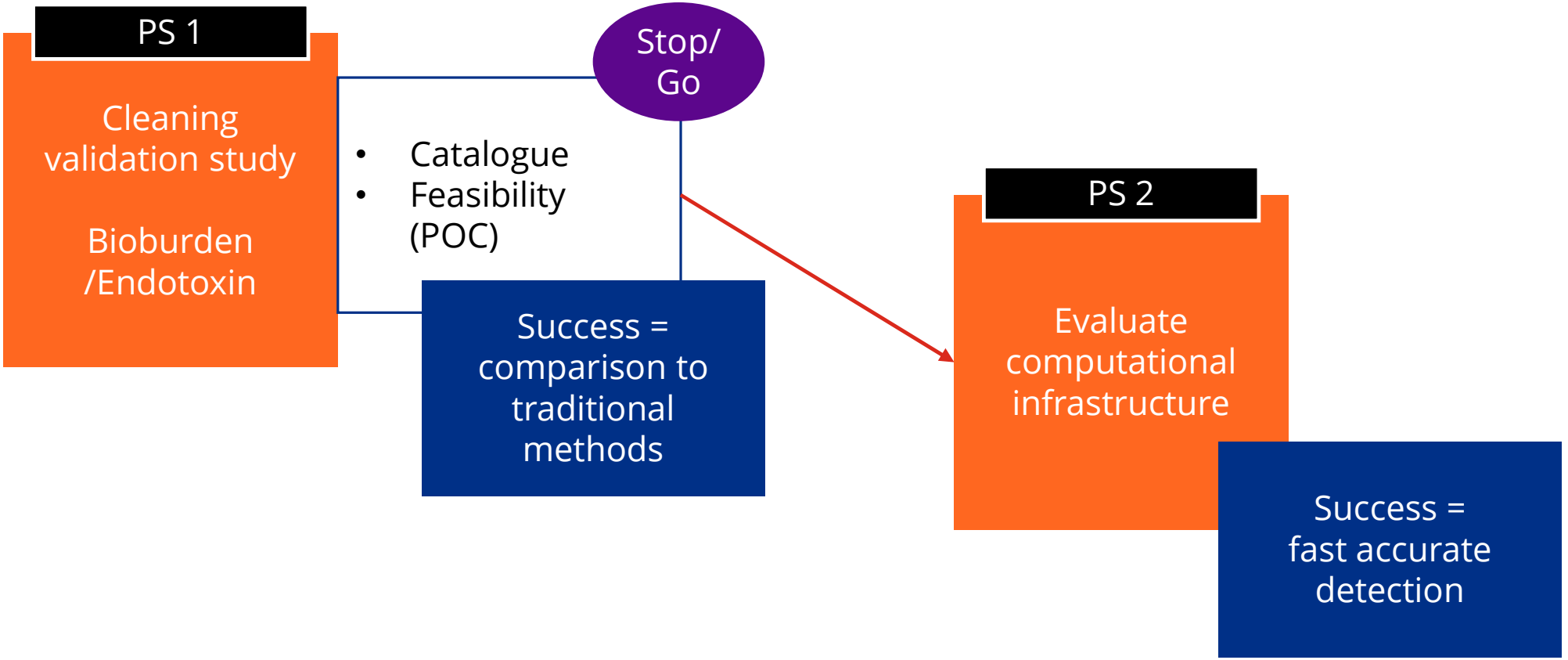
Development of Technologies for Accelerating Contamination Monitoring

4. A plan for **validation** of the solution involving validation experiments with cleaning validation samples (WFI) should be created. Some additional details are –
    a. Start with well-known contaminants derived as defined in the USP and European Pharmacopoeia compendial methods
5. Additional points to consider –
    a. Possibility of leveraging orthogonal sensors which complement each other, e.g. combine Raman and IR spectroscopic signals
    b. Assess if the combined spectra may provide additional features to enable detection of bioburden/endotoxin than individual sensor signals
6. It will be ideal for the solution to be compatible with existing production/laboratory systems to facilitate the easy generation of batch reports.

Desired Outcome

1. A **validated technology** which includes one or more sensors and computational model(s) whose output enables accurate detection of bioburden and endotoxin levels
2. The solution is evaluated and verified for compliance with applicable regulatory requirements through comparability with existing compendial methods

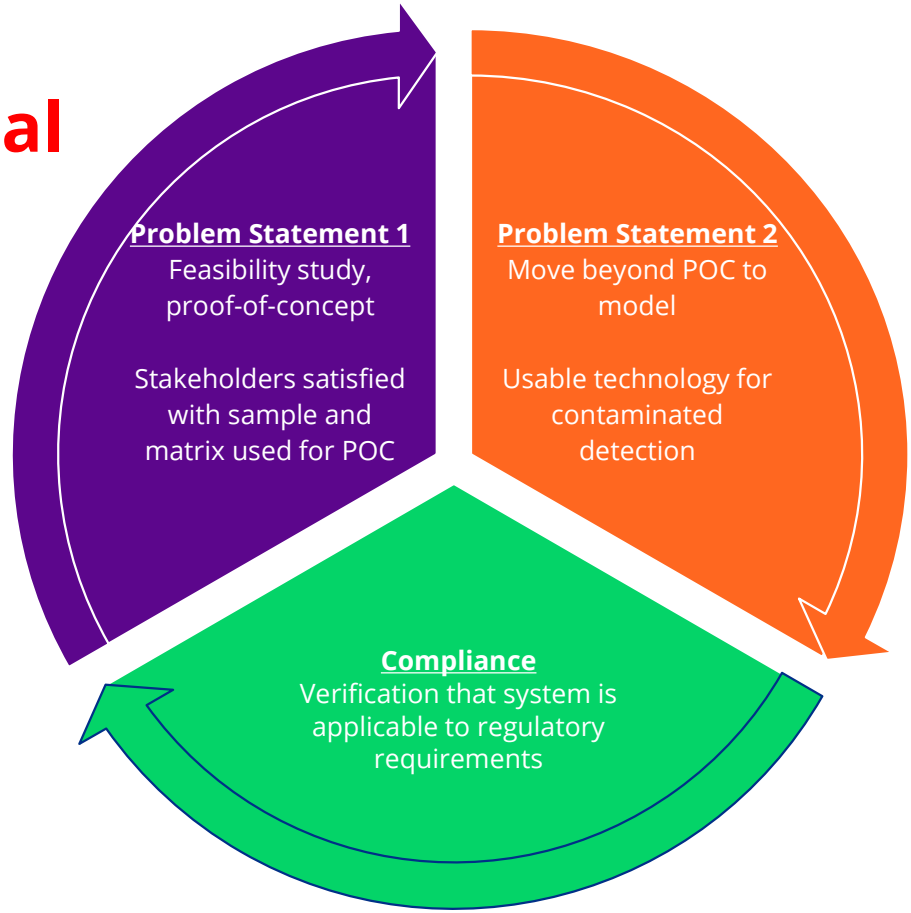
Development of Technologies for Accelerating Contamination Monitoring



CREATING GROWTH, ENHANCING LIVES

Development of Technologies for Accelerating Contamination Monitoring

Ultimate Goal



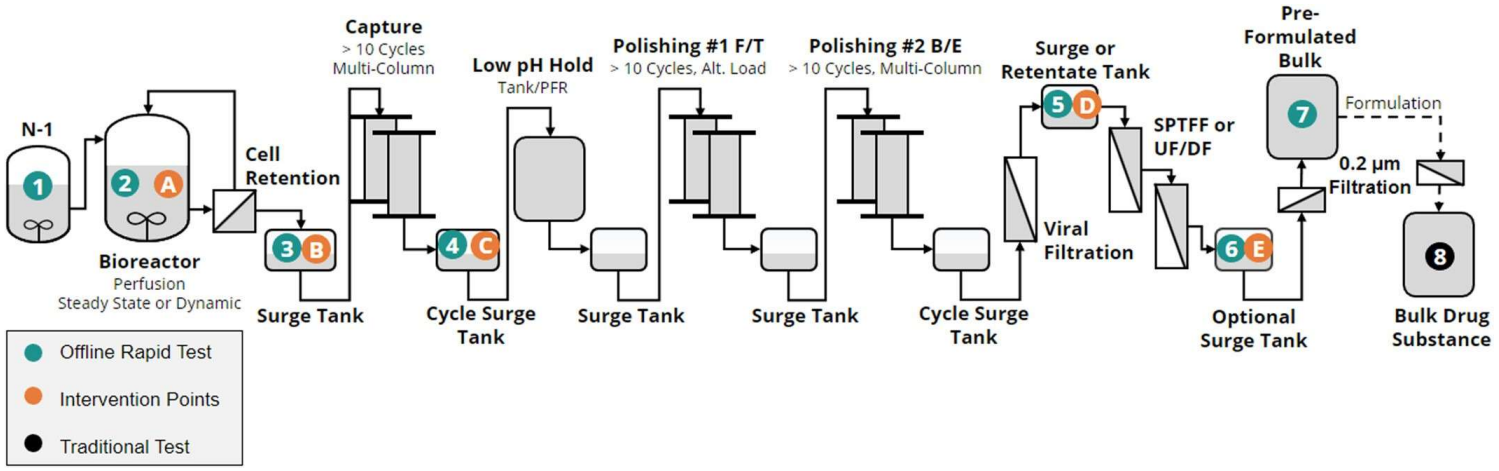
CREATING GROWTH, ENHANCING LIVES

Examples of Sources of Contamination and Testing/Intervention Points

Sources of Contamination

Contamination in pharmaceutical bioreactors can occur through various pathways and sources –

1. Airborne
2. Contaminated Raw Materials
3. Equipment and Facility
4. Operator
5. Cross-Contamination
6. Water



Example of testing/intervention points in continuous biomanufacturing from *Biotechnology Progress* (2024): e3431

Key References

Guidelines, best practices and current methods

1. EU Cleaning Validation Guideline: https://www.gmp-compliance.org/guidelines/gmp-guideline/eu-gmp-annex-15-qualification-and-validation
2. FDA Cleaning Validation Guideline: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-guides/validation-cleaning-processes-793
3. USP Chapter 61 – Microbiological examination of nonsterile products
   https://www.usp.org/sites/default/files/usp/document/harmonization/gen-method/q05b_pf_ira_34_6_2008.pdf
4. USP Chapter 85 – Bacterial Endotoxin
   https://www.usp.org/harmonization-standards/pdg/general-methods/bacterial-endotoxins
5. European Pharmacopoeia Chapter 2.6.12 – Microbiological examination of non-sterile products (microbial enumeration tests)
   https://ehpm.org/wp-content/uploads/2022/04/QG22_2-6-12_Microbiological_examination_of_non-sterile_products-microbial_enumeration_tests
6. European Pharmacopoeia Chapter 2.6.14 – Bacterial Endotoxin
   https://gmpua.com/Validation/Method/LAL/EUPHARMACOPOEIA.pdf
7. FDA research article on bacterial endotoxin assays: https://www.sciencedirect.com/science/article/pii/S092809872100018X
8. Articles on modern microbial detection methods: https://www.pda.org/pda-letter-portal/home/full-article/initial-evaluation-roadmap-for-modern-microbial-methods

   https://www.pda.org/pda-letter-portal/home/full-article/modern-microbial-methods-support-of-a-contamination-control-strategy

Sustainability

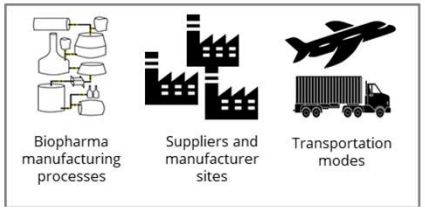
Sustainability

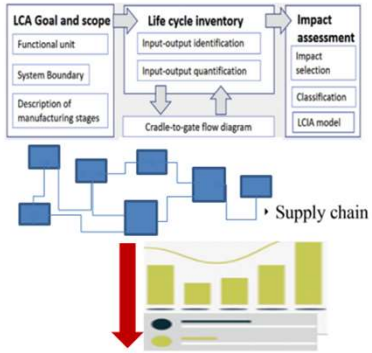
Biopharmaceutical and vaccine manufacture faces 2 key sustainability challenges – (1) Exploring resilient and sustainable supply chains and biomanufacturing facilities and (2) Evolution of Single Use Technology (SUT) and equipment.

In the **Sustainability** workstream, the starting point is a macro level view on what a **sustainable ecosystem for manufacture** constitutes, i.e. relationship between suppliers of raw materials/components, biomanufacturing operations to promote sustainability, optimisation of resource (energy, water) utilisation, productivity and waste management.

The 2nd strand is a fresh look at **SUT** and equipment through the lens of materials science while considering circular economy factors.

Common sustainability goals
Limit environmental footprint
Sustainable sourcing and circular economic solutions
Zero waste-to-landfill
Reduce GHG and carbon emissions

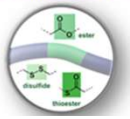




Main Indicator	Performance Metrics
Net CO_2 emission	Net CO_2 emission via LCA from "Cradle-to-Gate"
Revenue-Costs	Profit making potential
Technological feasibility	Potential scale of processes, efficiencies and product yields
Feedstock	Types, locations, sources, quantities
Supply security	Logistics, supply chain inventory management

Materials Innovation

Vitrimers



Chemo-Degradable Plastics

Close-the-Loop Polymers

CREATING GROWTH, ENHANCING LIVES

Call for Technologies on Wastewater Treatment/ Reduction/Recycling

Introduction

Different grades of water are utilised in biopharmaceutical manufacturing for various purposes, including cell cultivation, buffer preparation, cleaning and sterilisation of process equipment, cleaning of manufacturing facilities, e.g. cooling tower, etc. Water for injection (WFI) is used in the preparation of biopharmaceuticals while purified water is used in cleaning and in cooling towers. Although water is a renewable resource, freshwater is limited and its use requires energy and infrastructure for purification, recycling and disposal.

Problem Statement – Technologies for Wastewater Treatment/Reduction/Recycling

Wastewater can be recycled, disposed into the sewerage system or incinerated depending on the contaminants in the wastewater stream. Incineration of wastewater is the least desired but is sometimes necessary due to challenges in removing contaminants which are not allowable for discharge into the sewerage according to regulations. In Singapore, this regulation is the Sewerage and Drainage Act (Chapter 294, Sections 72 and 74) – Sewerage and Drainage (Trade Effluent) Regulations. Incinerated wastewater is typically aqueous-based containing organic compounds (e.g. guanidine, bioactive compounds) and salts from cell cultivation and purification processes. It does not contain prohibited organic compounds listed in Schedule 1 of the Sewerage and Drainage (Trade Effluent) Regulations, i.e. calcium carbide, flammable substances and radioactive materials.

Call for Technologies on Wastewater Treatment/ Reduction/Recycling

Scope

1. Development of wastewater treatment, reduction and/or recycling technologies for implementation in biopharmaceutical manufacturing facilities to reduce energy requirements and/or costs for water use, e.g. membrane filtration/distillation, supercritical water oxidation, etc. Recovery of high value raw materials from wastewater can also be considered.
2. The proposed solution should develop a prototype to process a few thousand litres per batch in a week which is scalable to few thousand litres per day
3. The proposed solution should aim to remove > 40% of water from the wastewater for recycling or discharge into the Singapore sewerage system, i.e. the removed water should meet discharge criteria: https://sso.agc.gov.sg/SL/SDA1999-RG5?DocDate=20161003)
4. Proposals should include analysis to describe process economics, energy and water resource use and GHG emissions

Desired Outcome

1. Reduce wastewater incineration in biomanufacturing facilities thus reducing GHG and carbon emissions from these facilities
2. Cost effective and sustainable solutions for wastewater treatment/reduction/recycling for implementation or commercialisation

Typical Equipment and Processes for Biologics and Vaccine Manufacture

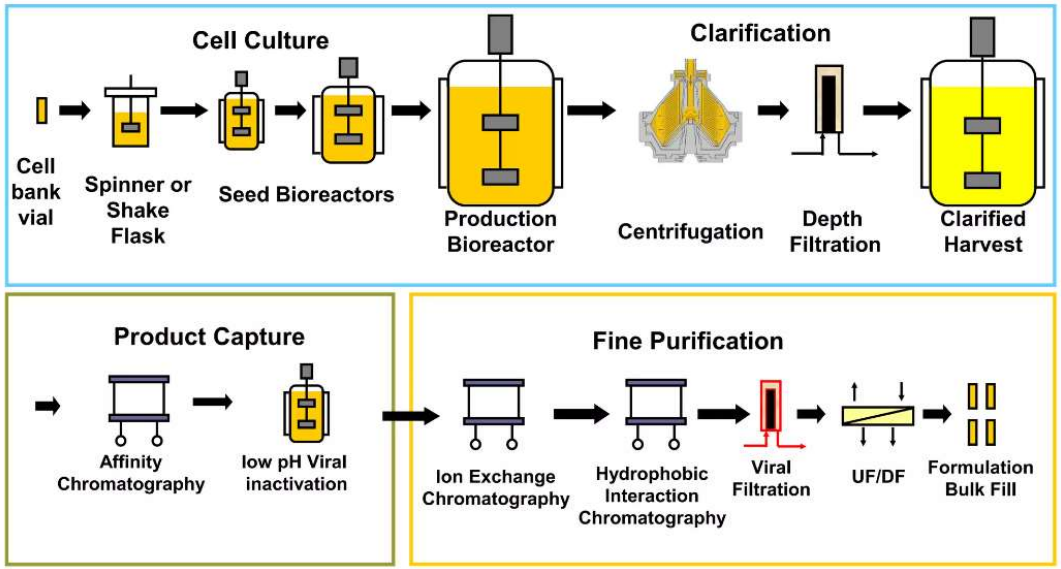


Image from Worcester Polytechnic Institute

Images from Samsung Biologics

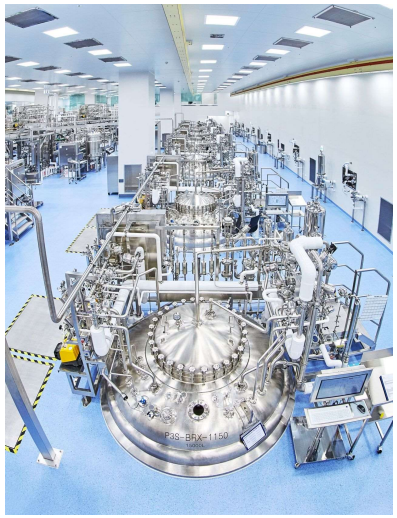


Image from Sartorius

Biopharmaceutical Wastewater Streams – Example 1

Main concern for this grant call is the process wastewater

Extracted from: dx.doi.org/10.1021/ie501210j Ind. Eng. Chem. Res. 2014, 53, 11571−11592

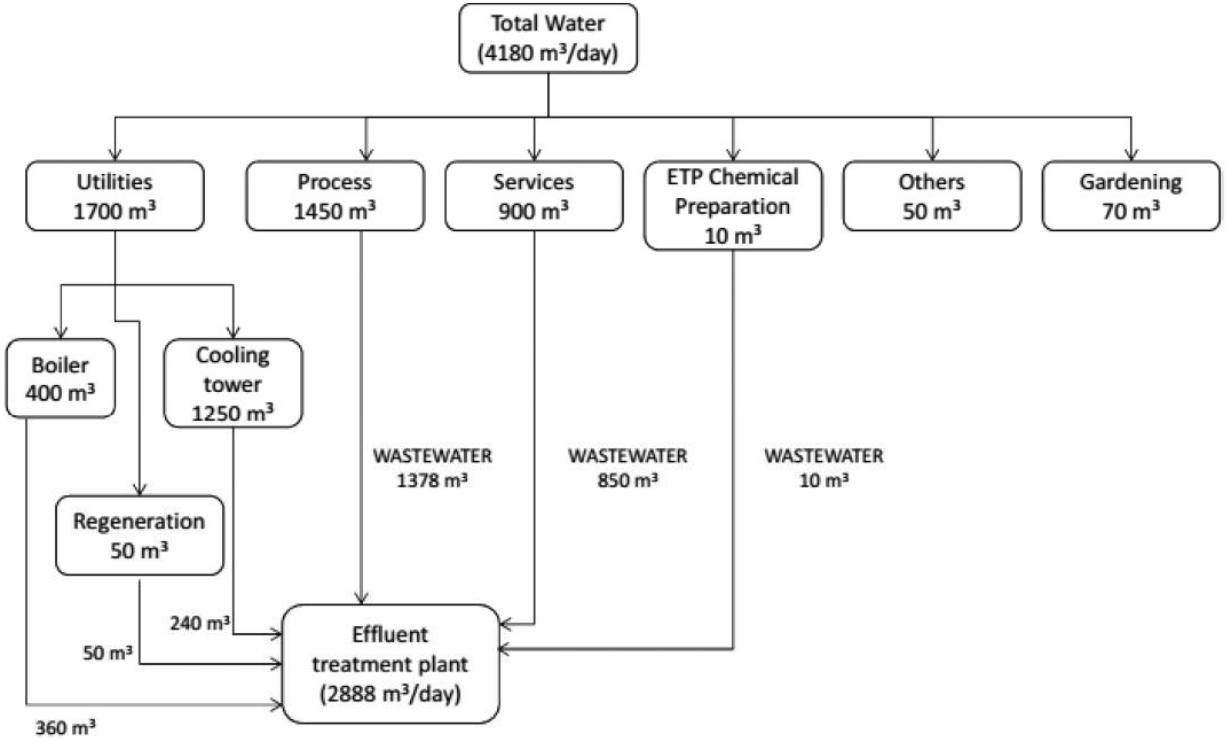


Figure 8. Water balance for a fermentation process manufacturing plant producing penicillin (ratio of consumption of process water to total water = 0.08). Adapted from ref 31. Copyright 2007 CPCB.

Biopharmaceutical Process Wastewater – Example 1

Extracted from: dx.doi.org/10.1021/ie501210j Ind. Eng. Chem. Res. 2014, 53, 11571−11592

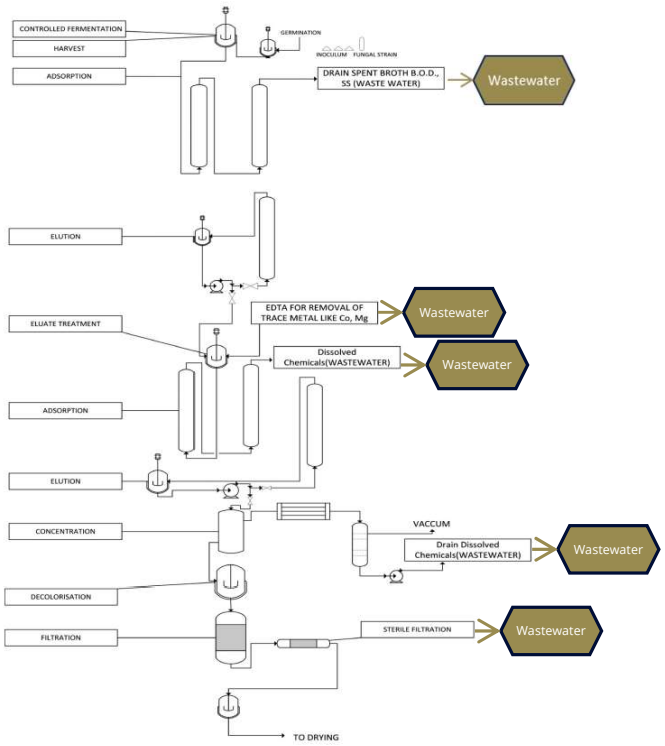


Figure 4. Streptomycin production and its recovery and purification from the fermentation broth. Adapted from ref 30. Copyright 1988−1989 CPCB.

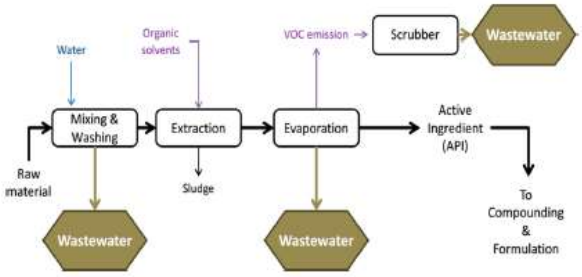


Figure 5. Process flow sheet diagram for natural/biological extraction process. Adapted from ref 29. Copyright 1998 U.S. EPA.

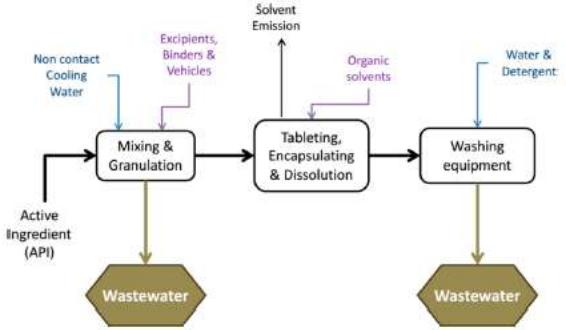
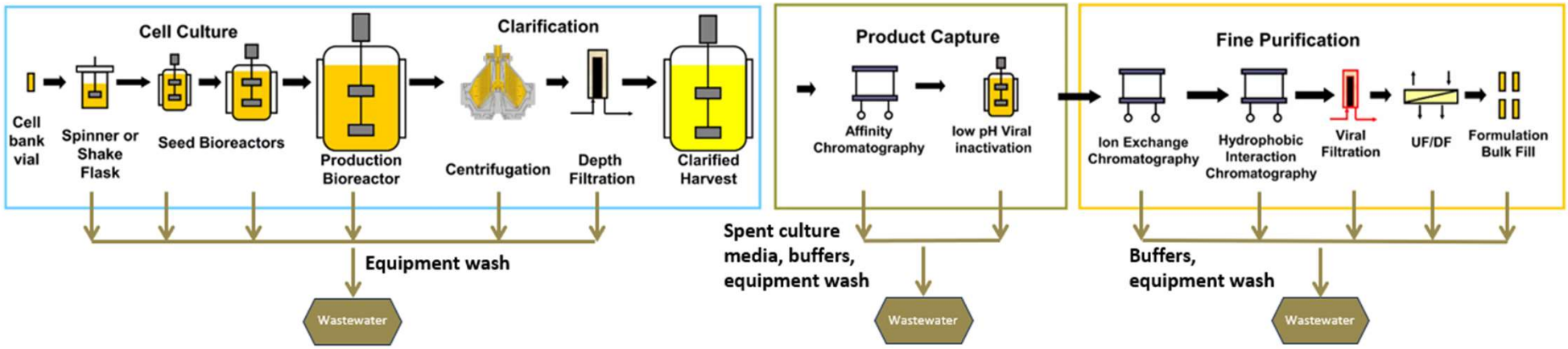


Figure 6. Process flow sheet diagram for the compounding/formulation process. Adapted from ref 29. Copyright 1998 U.S. EPA.

Biopharmaceutical Process Wastewater – Example 2



Wastewater Requirements for Sewerage Discharge

https://sso.agc.gov.sg/SL/SDA1999-RG5?DocDate=20161003

Trade effluent to be free of certain substances

9.—(1) Subject to any permission granted under regulation 11A, a person must not discharge or cause to be discharged into any public sewerage system, or any drain-line or sewer connected to a public sewerage system, any trade effluent which contains any of the following substances:	
(*a*)	any toxic industrial waste, unless the toxic industrial waste is treated and does not contain any substance listed in the Second or Third Schedule in a concentration greater than that specified in either Schedule for the substance;*[S 546/2024 wef 01/07/2024]*
(*b*)	calcium carbide;
(*c*)	petroleum spirit or other inflammable substance;
(*d*)	any organic compound specified in the First Schedule;
(*e*)	any substance that either by itself or in combination or by reaction with other waste or refuse may give rise to any gas, fume, odour or substance which is or is likely to be a hazard to human life, a public nuisance, injurious or otherwise objectionable, or which prevents or is likely to prevent entry by workmen maintaining or repairing the public sewerage system, into the public sewerage system;*[S 546/2024 wef 01/07/2024]*
(*f*)	yeast, spent or unspent molasses, crude tar, tar oil, crude oil, carbon disulphide, hydro-sulphide and poly-sulphide;
(*g*)	any radioactive material;
(*h*)	any waste or refuse liable to form a viscous or solid coating or deposit on any part of the public sewer or sewerage system;
(*i*)	any excessively discolouring substance;
(*j*)	[*Deleted by S 46/2013 wef 01/02/2013*]
(*k*)	any pesticide, fungicide, herbicide, insecticide, rodenticide or fumigant;
(*l*)	blood waste;
(*m*)	infectious waste;
(*n*)	any biological agent within the meaning given by section 2 of the Biological Agents and Toxins Act 2005;*[S 546/2024 wef 01/07/2024]*
(*o*)	any toxin within the meaning given by section 2 of the Biological Agents and Toxins Act 2005;*[S 546/2024 wef 01/07/2024]*
(*p*)	any animal waste, except in accordance with paragraph (2);*[S 546/2024 wef 01/07/2024]*
(*q*)	any chemical that is classified with hazard statement code H340, H350 or H360 under the ninth revised edition of the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) published by the United Nations in 2021;*[S 546/2024 wef 01/07/2024]*
(*r*)	any waste generated from a process that involves tissue digestion or tissue hydrolysis.*[S 73/2015 wef 13/02/2015]* *[S 546/2024 wef 01/07/2024]*

CREATING GROWTH, ENHANCING LIVES

Wastewater Requirements for Sewerage Discharge

https://sso.agc.gov.sg/SL/SDA1999-RG5?DocDate=20161003

any toxic industrial waste, unless the toxic industrial waste is treated and does not contain any substance listed in the Second or Third Schedule in a concentration greater than that specified in either Schedule for the substance

SECOND SCHEDULE

Regulations 9(1)(*a*), 10(1)(*a*) and 11A(1)(*b*)

MAXIMUM CONCENTRATIONS OF CERTAIN SUBSTANCES IN TRADE EFFLUENT

		Limit in milligrams per litre of trade effluent
(1)	Total Suspended Solids	400
(2)	Total Dissolved Solids	3,000
(3)	Chloride (as chloride ion)	1,000
(4)	Sulphate (as SO_4)	1,000
(5)	Sulphide (as sulphur)	1
(6)	Cyanide (as CN)	2
(7)	Detergents (linear alkylate sulphonate as methylene blue active substances)	30
(8)	Grease and Oil (Hydrocarbon)	60
(9)	[*Deleted by S 73/2015 wef 13/02/2015*]	
(10)	Arsenic	5
(11)	Barium	10
(12)	Tin	10
(13)	Iron (as Fe)	50
(14)	Beryllium	5
(15)	Boron	5
(16)	Manganese	10
(17)	Phenolic Compounds (expressed as phenol)	0.5
(18)	Fluoride (expressed as fluoride ion)	15

THIRD SCHEDULE

Regulations 9(1)(*a*), 10(1)(*a*) and 11A(1)(*b*)

MAXIMUM CONCENTRATIONS OF METALS IN TRADE EFFLUENT

	Limit in milligrams per litre of trade effluent
(1) Cadmium	1
(2) Chromium (trivalent and hexavalent)	5
(3) Copper	5
(4) Lead	5
(5) Mercury	0.5
(6) Nickel	10
(7) Selenium	10
(8) Silver	5
(9) Zinc	10

Note: Where 2 or more of the metals listed in the table are present in the trade effluent, the total concentration of the metals shall not exceed 10 milligrams per litre.

[S 546/2024 wef 01/07/2024]

Wastewater Requirements for Sewerage Discharge

https://sso.agc.gov.sg/SL/SDA1999-RG5?DocDate=20161003

any chemical that is classified with hazard statement code H340, H350 or H360

H340 May cause genetic defects.
H350 May cause cancer.
H360 May damage fertility or the unborn child.

- Any organisms =>BSL2
- API products
- Adjuvants
- Conjugates

any biological agent within the meaning given by section 2 of the Biological Agents and Toxins Act 2005;*[S 546/2024 wef 01/07/2024]*
any toxin within the meaning given by section 2 of the Biological Agents and Toxins Act 2005;*[S 546/2024 wef 01/07/2024]*

"biological agent" means —

(*a*) any micro-organism (including any bacterium, virus, fungus, rickettsia and parasite);

(*b*) any infectious substance (including any prion); or

(*c*) any component of a micro-organism or an infectious substance (but not including any toxin),

that is capable of causing death, disease or other biological malfunction in a human;

"biological agent waste" means any unwanted, unused or obsolete biological agent or any material or waste contaminated with any biological agent;

"toxin" means any poisonous substance that is produced and extracted from any micro-organism;

Administrative Notes

Eligibility

1. The Principal Investigator and Co-Investigators as defined in Grant Terms and Conditions must:
    a. Hold a primary appointment in a Singapore publicly funded research institution or an Institute of Higher Learning. The Principal Investigator must hold a primary appointment of at least 0.7 FTE in Singapore.
    b. Lead a laboratory or research programme which carries out research in Singapore
    c. Possess track record of leadership ability in coordinating research programmes and providing mentorship to research teams as well as having productive research outcomes. A track record in securing IRS will be advantageous.

2. Collaborators as defined in Grant Terms and Conditions are not eligible to receive funding
    a. Companies can participate in projects only as collaborators

3. Exceptions to the above eligibility criteria will be considered on a case-by-case basis. Please submit a request to the BioPIPS Programme Office at least 7 days before the closing date of the grant call.

Important Notes

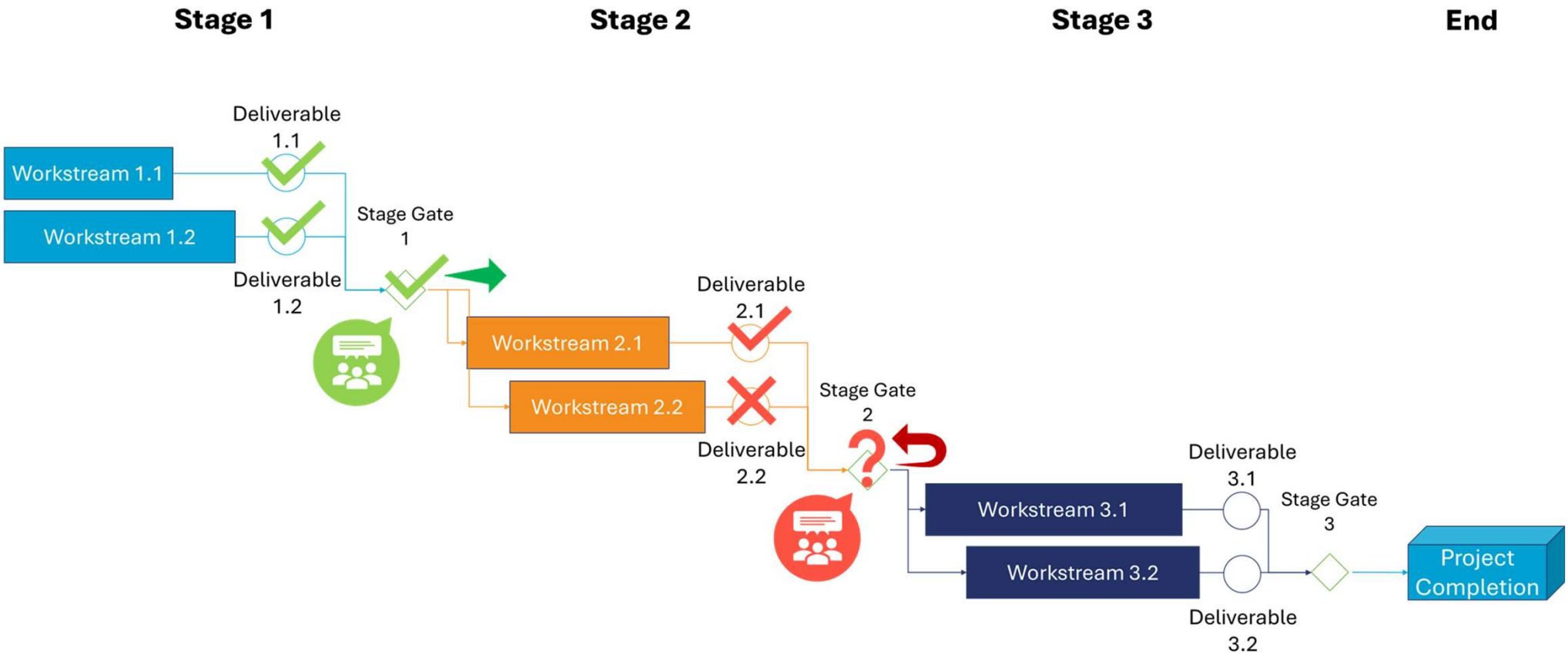
1. Applicants must use the latest version of the Letter of Intent (LOI)/proposal template

2. Submissions should clearly state milestones and deliverables. Industry collaborations are strongly encouraged.

3. Applicants shall comply with grant terms and conditions, including prevailing regulations

CREATING GROWTH, ENHANCING LIVES

Example of Stage-Gated Project Management



Evaluation Criteria

1. Relevance to Problem Statement(s)
2. Potential for commercial adoption
3. Scientific quality and innovativeness
4. Experience and expertise of the team
5. Effectiveness of project management
6. Appropriateness of the requested budget
7. Strength of intellectual property (IP) strategy
8. International competitiveness

CREATING GROWTH, ENHANCING LIVES

Contact Us

For all enquiries, contact the BioPIPS Programme Office at –

biopips@bti.a-star.edu.sg

BioPIPS website address –

https://www.a-star.edu.sg/bti/programmes-in-bti/biologics-pharma-innovation-programme-singapore-(biopips)

CREATING GROWTH, ENHANCING LIVES

CREATING GROWTH, ENHANCING LIVES

Bioprocessing Technology Institute
BTI

THANK YOU

For more information, visit www.a-star.edu.sg

ASTARSG ASTARTV