DIFFERENCES IN BSO ROLE IN THE PHARMACEUTICAL INDUSTRY VERSUS ACADEMIC LABORATORIES

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Sanofi Pasteur Toronto

Lawson Health Research Institute

Hospital-based research institute

- **Basic and translational research**
  - Using risk group 2 pathogens and toxins
- **Implemented biosafety program**
  - Applied for HPTA RG2 licence (CL2 laboratories)
- **Regulatory oversight: HPTA, HPTR, CBS (PHAC, CFIA)**

LAWSON
HEALTH RESEARCH INSTITUTE

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Down to the US

Duke University (in North Carolina)

Duke Human Vaccine Institute

Academic research institute

- **Basic and translational research focused on vaccine development**
  - Using risk group 2 and 3 human and animal pathogens and toxins
    - Including select agents (a.k.a SSBAs)
- **Regulatory Oversight: BMBL as guideline, FSAP (CDC, USDA)**

Duke Human Vaccine Institute
Duke University School of Medicine

Back to Canada

Sanofi Pasteur (Toronto)

Sanofi Pasteur

Biopharmaceutical Company

- **Vaccines division of Sanofi Aventis**
- **Toronto site**
  - Produces components for several vaccines (pertussis, diphtheria, tetanus, polio)
  - R&D department
  - Quality Control (QC) labs and vivarium

Biohazards at Sanofi Pasteur

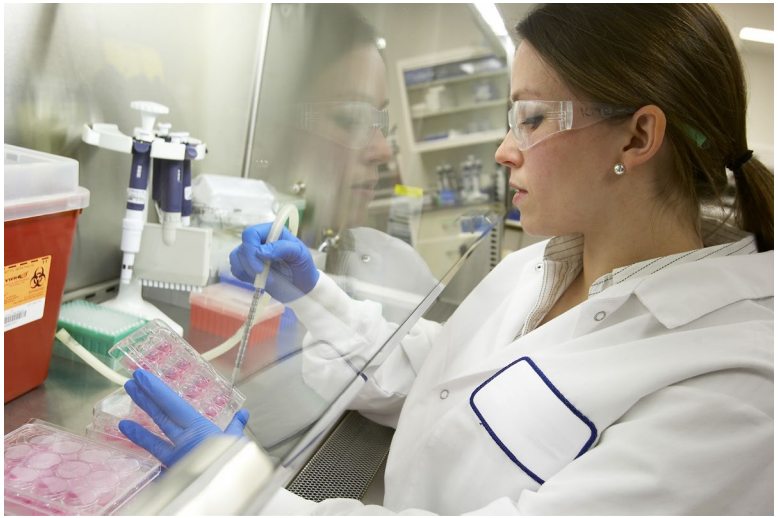
- **Risk group 2 human pathogens and toxins**
  - Risk group 2 HPTA licence (CL2-laboratories and large-scale)
- **Large-scale production**
  - Up to 4000L fermenters
- **R&D activities**
  - Various risk group 2 pathogens and toxins (vaccine development, product testing)
- **Quality control testing**
  - In vivo and in vitro

So, what's the difference?

Several differences from a biosafety perspective…

Scale of work

Lab scale

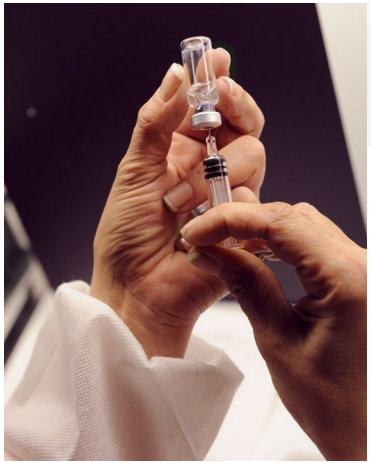


Production (large) scale

Large-scale Production

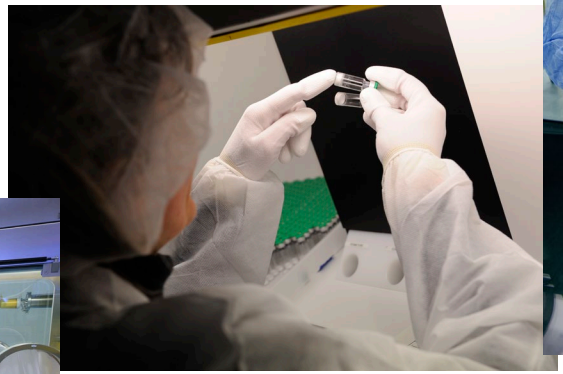
Regulatory Oversight

- **Not just biosafety regulations!**
- **Products intended for human use: human safety is the priority**
  - Health Canada, FDA requirements



Regulatory Oversight

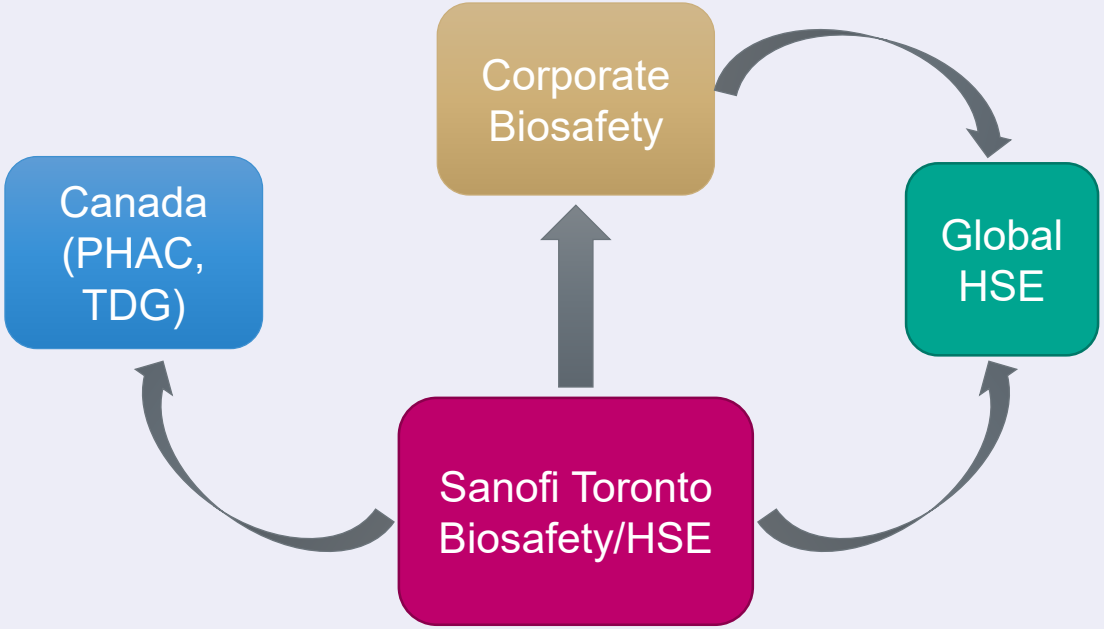
- **Sometimes Biosafety ≠ Product Safety!**
  - Regulatory requirements can contradict; harmonizing is challenging but necessary
- **GMP vs Biosafety**
  - Change the ‘vs’ to ‘and’



Corporate Safety Program

- **Sanofi Pasteur is a global company**
  - Corporate safety requirements need to be met
    - To ensure harmonization worldwide (important for production consistency)
  - How to harmonize with local requirements must always be considered
- **Health, Safety, and Environment (HSE) as a standalone department**
  - versus being part of another department (e.g., facilities, HR)

Biosafety Program



Personnel

- **Biopharmaceutical manufacturing = large diversity of personnel**
  - Production, quality, R&D, filling and packaging, custodial, ERT, facilities/maintenance
- **Delivering biosafety training can be challenging**
  - Customize for different audiences – what's relevant to each group?
  - Shift work – how to reach everyone?
  - Risk-based approach

Biosafety Advantages in Manufacturing

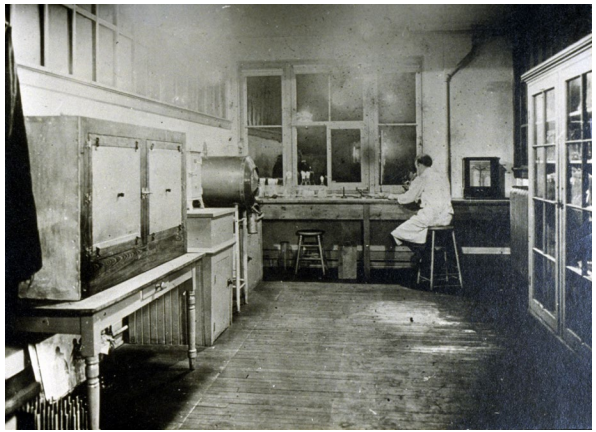
- **Sometimes biosafety is enhanced by product safety requirements**
  - E.g., PPE, facility design, personnel flow, disinfection and decontamination
- **Fewer research activities; less variety of pathogens/toxins used**
  - E.g., production activities don't change very often, so easier to assess risk and mitigate (vs dynamic nature of research)

Summary

What I've learned…

- **Academia ≠ Industry!**
- **Scale of biosafety program very different**
- **In general, more regulatory requirements / oversight**
  - And corporate requirements
- **Diversity of personnel**
- **Overall, it's a different biosafety experience…**

…BUT WITH SIMILAR PAST CHALLENGES AND ONGOING IMPROVEMENTS



THANK YOU!

SANOFI PASTEUR