Fast Science:
EHS Challenges in Biotechnology Research & Development Startups

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Introduction

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- Currently an EH&S Consultant w/ Harris & Lee Env. Sciences
- Previously spent 16yrs in bench/wet lab work and lab management
- Moved over to EH&S full time in 2015

Where to Start

Who knows about EH&S?

What do current start-ups look like?

- Small
- Agile
- Innovative
- Minimal management oversight
- Individual contributors
- Minimal EHS expertise
- Cash flow (?)

Our Focus Today

Regulatory Knowledge Gaps

Safety Misconceptions & Identifying Hazards

Building Onsite Safety Programs

Regulatory Knowledge Gaps

Environ-mental Permitting

- EPA ID Number
- Facility Registration/Fire Permits/ Special Permits (City/County)
- California Environmental Reporting System (CERS)
- Medical Waste Permits (County)
- Wastewater Permitting (local)
- Air Quality Management District (Regional)

And more….

Cal/OSHA Safety Programs

- Injury Illness Prevention Plan
- Emergency Action Plan
- Fire Prevention Plan

Applicable to all employees

- Bloodborne Pathogens Exposure Control Program
- Chemical Hygiene Plan
- Hazard Communication
- Personal Protective Equipment

Applicable to lab employees & other staff entering lab areas

- Radiation Protection
- Respiratory Protection
- Hearing Protection
- LOTO

May apply to a variety of employees / tasks

The list goes on….

Hazardous & Medical Waste Management

- Waste labelling
- Liquid Biohazardous Waste
- Hazardous Waste Determinations
- Are pipette tips sharps?
- Coordinating with waste vendors
- Manifest management & training requirements

Safety Misconceptions & Identifying Hazards

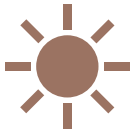
Perceptions of what is a Hazard

Biological

Chemical

Radiation

Sound



UV

Equipment

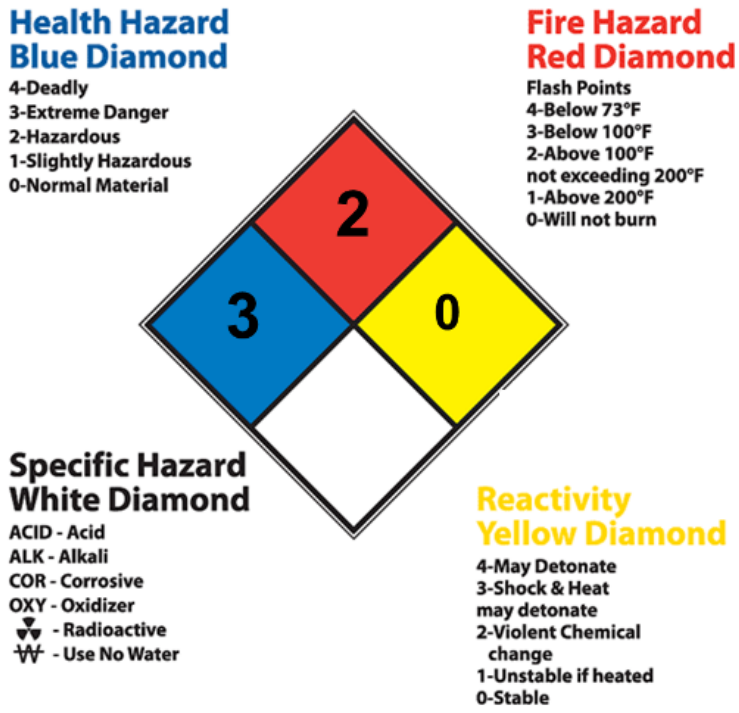
Other

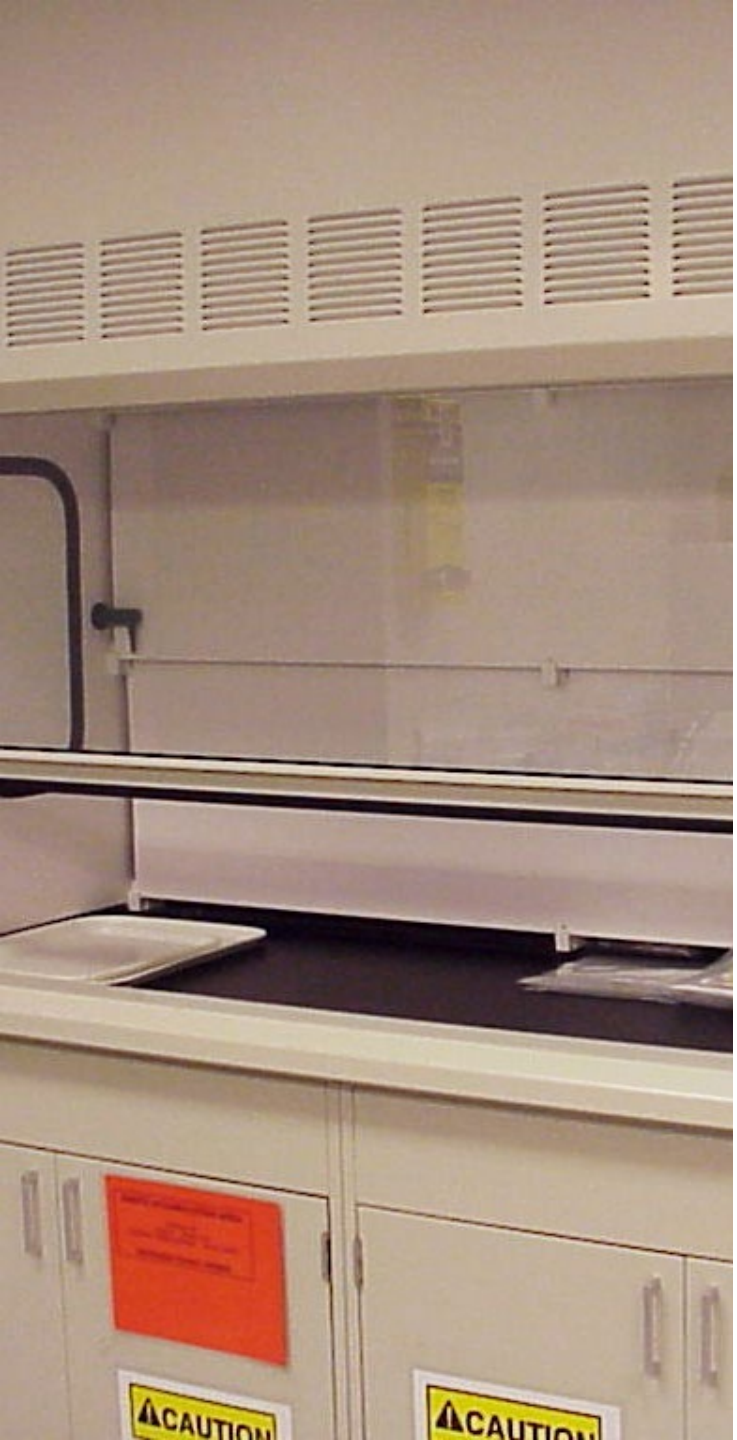
Hazard Communication
GHS vs. NFPA Numbering Systems

Safety Data Sheets - What the numbers mean.

GHS Category	Hazard Level
Cat. 1	Severe hazard
Cat. 2	Serious hazard
Cat. 3	Moderate hazard
Cat. 4	Slight hazard
Cat. 5	Minimal hazard

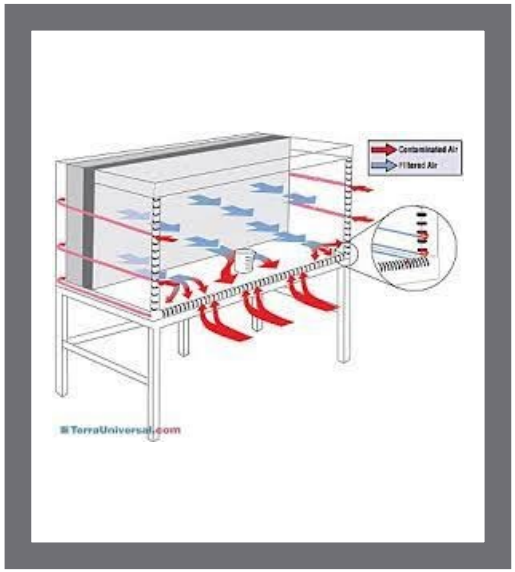
NFPA Diamond





Types of Hoods

- Fume Hoods, snorkel exhausts, benchtop, etc…
  - Tied into the HVAC system or filtered?
  - If filtered, what chemicals are they appropriate for?
- Biological Safety Cabinets (BSCs)
  - Type of filtration
  - Air recirculation
  - Exhausted?

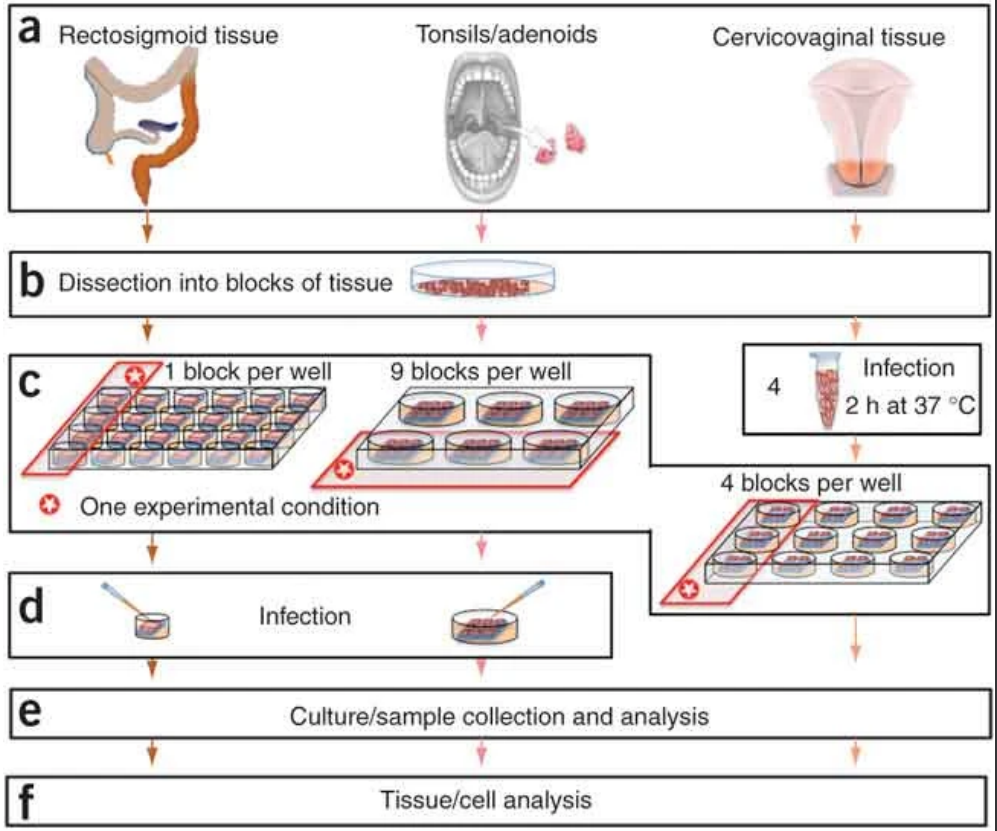


Types of Hoods

- Laminar flow/clean hoods
  - Protect samples only, not the user
- Cage change stations
  - Not the same as a BSC!
  - Does not provide the same level of protection
- Downdraft tables
  - Tied into HVAC system or filtered?
  - Are they being used appropriately for the specific hazards

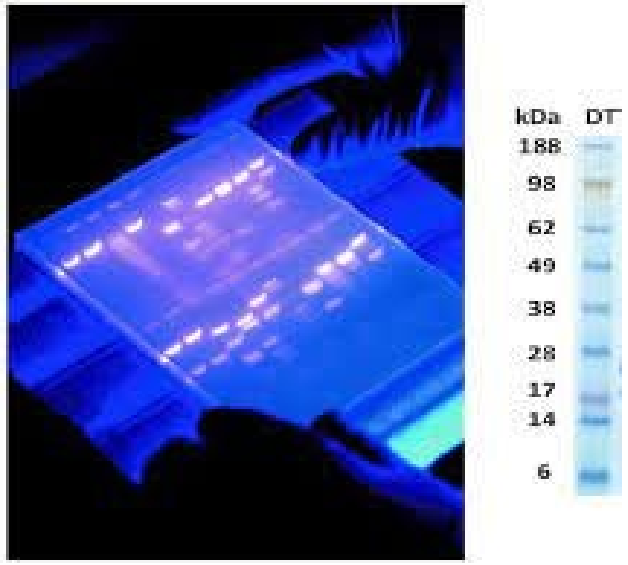
Determining BSL & Human Sample Safety

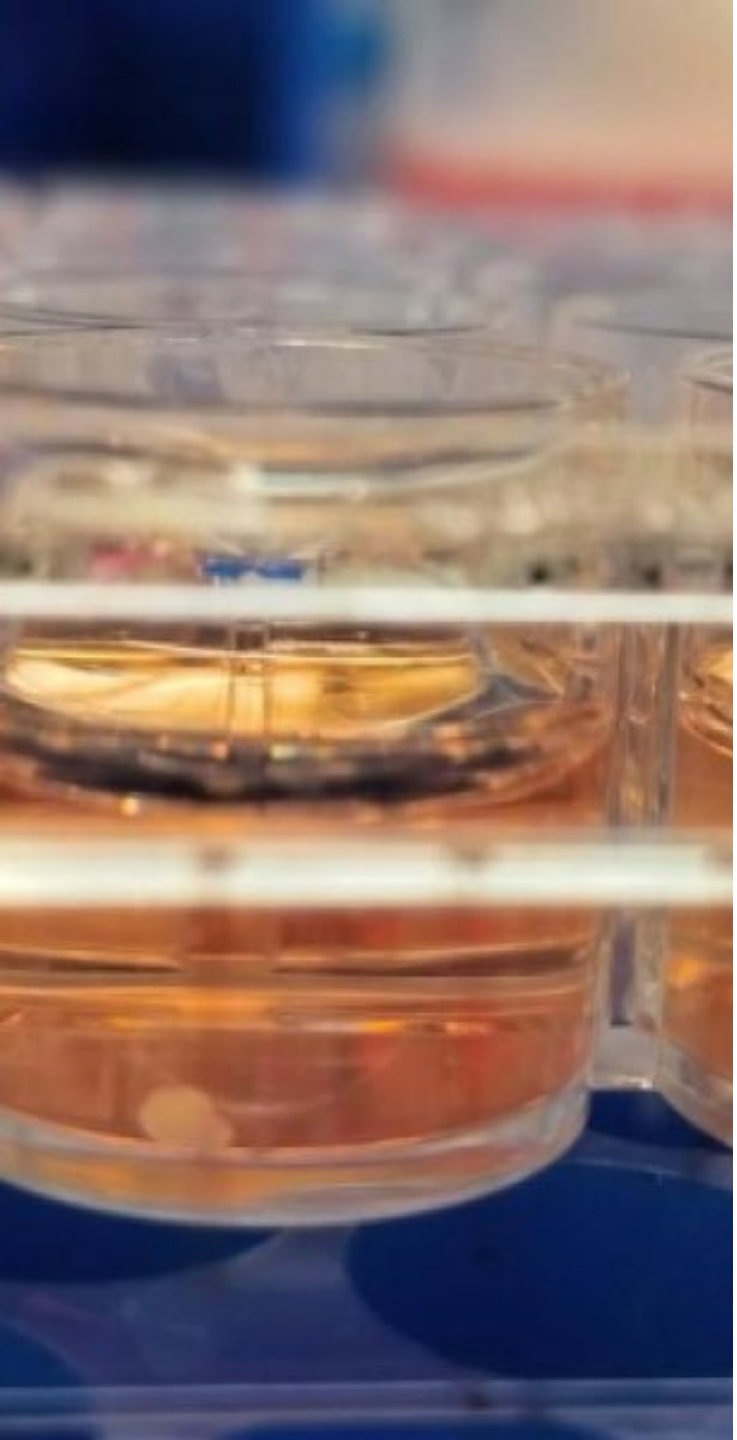
- Risk Groups vs Bio Safety Level
- Human Samples
  - What if they have been “tested”?
  - Human TC lines



Key Phrases

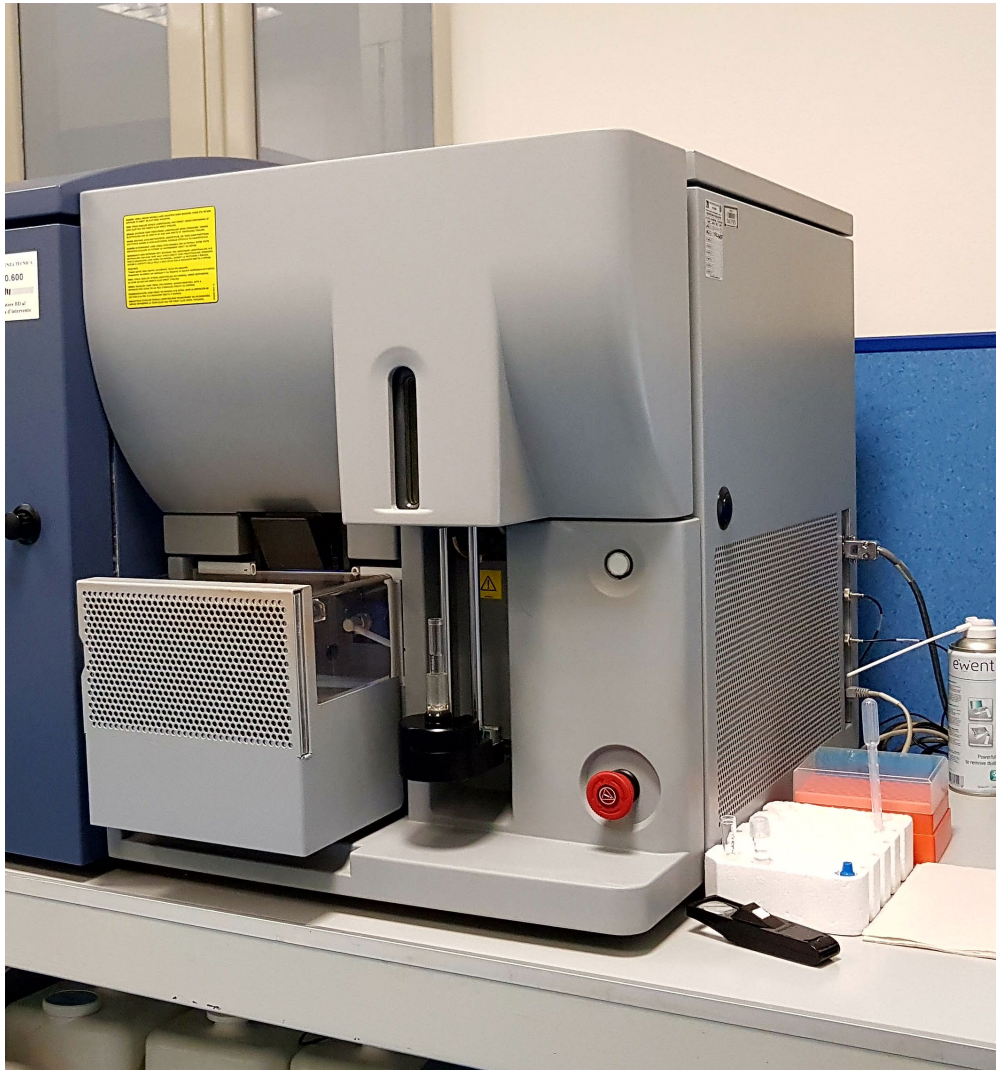
- DNA/RNA Extraction & Purification
  - Kit components & hazards
- Protein Extraction
  - Source material
- Gels & Staining
  - Intercalating agents
  - Acrylamide, UV
- Microbiology/Microbiome
  - Bacteria, fungi, pathogens?
  - Determining Risk Group / Bio Safety Level





Key Phrases

- Tissue culture
  - Cell type & origin
  - Known viral infections
- Transformation & Transfection
  - Lentivirus
  - Other viral vector systems?
  - DNA plasmids
- Oncology
  - Chemotherapeutics
  - Oncogenic cells/tissues



Key Phrases

- DNA Sequencing
  - Formamide wastes
- Cell Sorters/FACs (Flow Cytometry)
  - Aerosol hazards
  - Containment or built-in aerosol management systems
- Histology
  - Micro- & Ultratomes
  - Fixatives, solvents, formaldehyde

Key Phrases

- Vivarium / Insectary
  - Regulated species
  - Animal allergens
  - Zoonotic diseases
  - Occupational Health Programs
  - Animal escape/release controls
  - Sharps/bites/scratch injuries
  - Shedding of infectious or hazardous chemical agents after inoculation
  - Managing wastes

Building Onsite Safety Programs

New Company Case Study

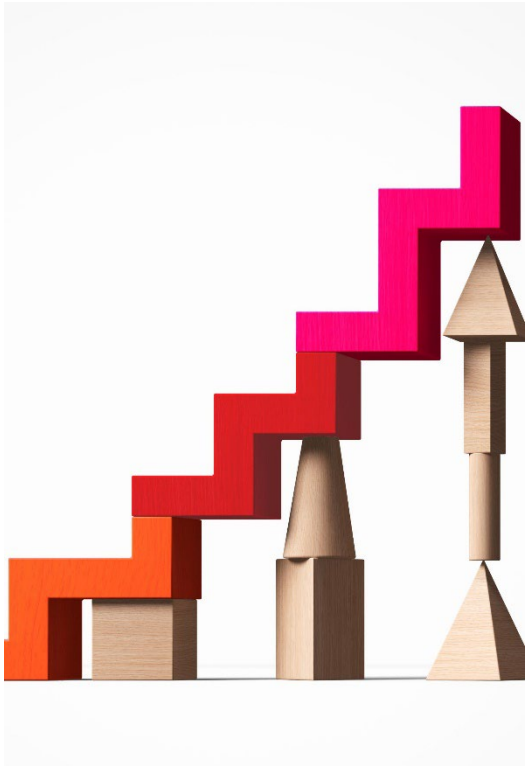
The New Safety Officer

Setting up Safety Programs

- Written Programs & program reviews
- Assigning Responsibilities
- Training Employees & Managers
- Creating an onsite Safety Team
- Periodic Inspections
- Setting expectations

Scaling Safety Programs

- Chemical Inventory & SDS management
- Training Programs
- Spreading out responsibilities
- Growing your Safety Team



Thank you

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