



## Top Safety Considerations in Biopharmaceutical Manufacturing

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Katie Keller is the Director of Quality and Safety at Asahi Kasei Bioprocess America. She has 12 years of experience designing and developing Quality Management Systems, and has led two organizations through the transition to new ISO standards. She is a Certified Quality Auditor (CQA) through the American Society for Quality (ASQ), and has extensive experience auditing to ISO 9001, TS 16949 (now IATF 16949), ISO 14001, and AS9100 standards. She holds an MA in Japanese Language and Society from the University of Sheffield.

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Addressing the health and safety concerns of biopharmaceutical manufacturing for individuals inside and outside the workplace is a vital first step in prioritizing awareness of the industry's processes and preventing error-driven accidents in each situation. The following is a list of top safety concerns for individuals in the biopharmaceutical workplace:

### THE FIVE MOST COMMON SAFETY CONCERNS

**Combustible Materials and Fire Safety:** The manufacturing process requires the storing and transporting of highly flammable liquids and combustible solids. Uncontrolled fires can easily spread, damage other parts of the facility, and create further secondary accidents.<sup>1</sup> Burns, smoke inhalation, and explosions from these accidents may lead to serious injury or potentially fatal consequences for workers.

**Carbon Monoxide:** Carbon monoxide is a gas that is able to bind with iron. Due to the nature of the industry, misuse of chemicals can trigger reactions that result in carbon monoxide. Colorless and odorless, it is particularly lethal to humans and can result in "weakness, dizziness, tiredness, vomiting, and death."<sup>2</sup>

**UV Radiation:** Radiant energy is used in some operations of biopharma manufacturing such as for the production of Vitamin D. The three types of ultraviolet light are UV-A, UV-B, and UV-C. These are transferred using electromagnetic waves and vary in risk. However, even the least dangerous, UV-A, when exposed over long periods of time, can result in cataracts in the eye.<sup>3</sup> Other forms of radiation have also been shown to burn the eyes and skin and increase the risk of skin cancer.

**Hazardous Chemicals:** Hazardous raw materials are routinely dispensed, transported, and stored in upstream and downstream operations. When handling liquid chemicals, workers must practice correct procedures to prevent accidental spillage and mixing. Dry chemicals are also part of the production process and pose a toxic threat due to its dust particulate components. Exposure and inhalation can ultimately lead to respiratory irritation.<sup>4</sup>

**Highly Potent Active Pharmaceutical Ingredients (HPAPI):** HPAPIs are pharmaceutical compounds that, at very low concentrations, display a biological reaction. With advancements in pharmacology research, the HPAPI market is rapidly growing and is projected to reach "close to 10% annual growth."<sup>5</sup> Along with their increasing demand, HPAPIs "have complex structures requiring a multi-step process."<sup>6</sup> Therefore, their handling and containment requires strict restrictions, specific parameters between product and operator, expertly trained personnel with knowledge in emergency response communications, extensive cleaning to prevent contamination and to provide a safer environment for staff, and close evaluations and assessments by manufacturers.

### Questions?

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<sup>1</sup> <https://www.jensenhughes.com/insights/understanding-the-risks-of-pharmaceutical-manufacturing>

<sup>2,3</sup> <https://www.triumvirate.com/blog/top-safety-risks-pharmaceutical-manufacturing>

<sup>4</sup> Millipore Sigma. Operator Safety in Biopharmaceutical Manufacturing: The Role Raw Suppliers Can Play in Contributing to a Safer Production Environment.

<sup>5,6</sup> <https://www.pharmaceutical-technology.com/sponsored/hpapi-dealing-with-containment-challenges>



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### STRATEGIES TO MITIGATE SAFETY RISKS

Protective equipment for manufacturing employees or anyone who routinely handles drugs post-production are essential in protecting the health and safety of workers. To reduce the risk of exposure, workers should wear high quality, recommended PPE (Personal Protective Equipment) to maintain sterility:

- » Eye and face protection (e.g., goggles and face shields)
- » Gloves
- » Long-sleeved lab coats, gowns, and coveralls
- » Shoe covers
- » N95 Respirators and PAPRs

PPE has specific requirements based on the material being handled. Depending on the chemical and organism, as well as the production process, employers should ensure that workers have “access to high quality and durable pharmaceutical PPE that provides adequate protection without impairing worker mobility, gross motor function, vision, productivity, and general comfort.”<sup>7</sup>

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<sup>7</sup> <https://int-enviroguard.com/blog/5-top-safety-risks-in-pharmaceutical-manufacturing/>



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Advanced technology is a further added safety byline recently implemented into the biopharmaceutical manufacturing sector to greatly reduce human error and drive efficiency. User safety is a priority in manufacturing facilities coupled with efficiency improvements for the handling of raw materials. Bulk handling technologies are used as a means to prepare large volumes of buffers in both upstream and downstream processes. “For a large-scale production facility, this could equate to upwards to 1-2 million liters of buffer annually.”<sup>8</sup> The use of AI-driven systems in handling these materials means less spillage, and dangerous product mix ups, as well as safer liquid withdrawal.



Practicing regimented safety guidelines and implementing strict regulations not only prevents harmful bodily accidents, but also reduces future costs and facility/equipment damages. Facilities that routinely use chemicals in production should have all the proper safety technology and notices in their delegated spaces. This includes carbon monoxide detectors on doors, and caution signs to indicate the presence of carbon monoxide or UV-rays in the lab.

Workers should also be trained and follow OSHA Guidelines, a must for basic laboratory safety:

- » Keep a tidy work area and immediately clean spills or messes according to containment
- » Wash hands frequently
- » Ensure containers are labeled correctly and properly stored
- » Wear personal protective equipment (PPE)

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*Due to handling hazardous chemicals, workers put at risk should have access to and familiarity with Material Safety Data Sheets.*

- » Ensure safety data sheets are always easily accessible
- » Wear a laboratory coat and do not wear clothes that expose the skin
- » Never eat or smoke in the laboratory
- » Regularly check that all equipment is safe to use, and ventilation systems are working
- » Keep entryways clear
- » Place eye and hand washing stations in close vicinity to the work area

Risk assessments are a further preventative action regularly executed to “determine if any event or substance needs to be altered or eliminated.”<sup>9</sup> OSHA will monitor workplaces to guarantee that these risk assessments are completed.

Due to handling hazardous chemicals, workers put at risk should have access to and familiarity with Material Safety Data Sheets. A Safety Data Sheet identifies chemicals and substances, ingredients, and composition of said substances and safety hazards, toxicology report, handling and storage instructions, personal protection requirements, disposal methods, first aid guidelines, exhibits, and the provider’s contact information.

Biopharmaceutical manufacturing personnel that understand, analyze, review, and adapt accordingly to health and safety data prevent chemical spills into the surrounding environment or exposure of hazardous organisms to individuals and populations outside of the facility. As the industry grows exponentially, layering multiple preventative measures helps to mitigate risks to the manufacturing process – not only protecting staff, products, and the facility but also our communities.



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<sup>9</sup> <https://www.moravek.com/pharmaceutical-manufacturing-safety-considerations/>