

# Pathmaker

## Core Competency Checklist

Core competencies represent the minimum requirements for a Pathmaker-approved training program. The Pathmaker Core Competency Checklist defines the areas that *must* be included in a proposed curriculum, with specific examples in italics of focus areas that *may* be included to satisfy that required area. There are distinct core competencies identified for the PathmakerBIO and PathmakerTECH tracks. In response to industry needs, training providers may also propose new tracks through the PathmakerOPEN track.

### For Fund-seeking Organizations

MLSC program staff will coordinate a site visit to review the program at a mutually agreed upon time once the training program is fully operational. Applications for funding based on submission for the open track for roles beyond biomanufacturing and medtech manufacturing will still include a site visit and potential Pathmaker certification.

### For Non-fund-seeking Organizations

Training providers that are running existing programs of any length that still satisfy the Pathmaker Core Competencies should apply for Pathmaker validation through a simplified online application. The MLSC will review these applications as they are received and coordinate a site visit to process approval. Pathmaker-validated programs will be marketed to life science companies in the Commonwealth and beyond through the MLSC website including an interactive map and training provider listing.

## PathmakerTECH

This track focuses on preparing students for careers in the manufacturing industry by providing them with hands-on training in essential technical skills. Students will utilize cutting-edge technology to design and manufacture a wide range of products. Career examples include manufacturing technician and maintenance technician.

### General Competencies

- Career track options: *example positions, average wages, company info, potential career paths*
- Basic professional skills: *soft skills, computer literacy, meeting etiquette, communication, teamwork, problem-solving, resume/interview, time management, 5S / Lean production*

### Role Specific Competencies

- Good Documentation Practices: *following standard operating procedures (SOPs)*
- Clean room/sterilization: *gowning, equipment sterilization*
- Quality and Regulatory: *statistical process control, cGMP, health and safety, OSHA*
- Components and materials: *sensors, basic metallurgy, ceramics*
- Automation and processes: *robotics, technical drawings, basic electricity, electronics, mechanics, electromechanical assembly*

### Optional Company-Specific

- geometric dimensioning and tolerancing, 3D printing, other core skills deemed necessary by a partner employer*

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## PathmakerBIO

This track offers a comprehensive introduction to the field of biomanufacturing. It covers various applications of biotechnology and includes a practical laboratory component that equips students with the necessary skills for pursuing various related roles such as a biomanufacturing technician or biomanufacturing associate.

### General Competencies

- Career track options: *example positions, average wages, company info, potential career paths*
- Basic professional skills: *soft skills, computer literacy, meeting etiquette, communication, teamwork, problem-solving, resume/interview, time management, 5S /lean production*

### Role Specific Competencies

- Good Documentation Practices: *following standard operating procedures (SOPs)*
- Lab math: *unit conversion, dilution, molarity, calculations*
- Clean room/sterilization: *gowning, equipment sterilization, autoclave, filtration, sterile welding*
- Culture techniques: *cell, bacterial, yeast, freeze/thaw, passaging, media prep, aseptic technique*
- Overview of assays and protein purification: *HPLC, MALDI-TOF MS, microscopy, cell lysate, AKTA, TFF, separation, detection, quantification of proteins, SDS-PAGE gels, Western blot, ELISA, PCR, UV-vis spectrophotometry, centrifugation, pH measurement*
- Overview of product classes: *cell and gene therapy, biopharmaceuticals, mRNA, vaccine production*
- Quality and Regulatory: *cGMP, critical quality attributes, critical process parameters, efficacy, safety, environmental monitoring*
- Equipment and process: *bioreactor function, basic process monitoring, feedback, and control loop systems*

### Optional Company-specific

- Fermentation, mixing and aeration, yield and productivity, DNA isolation, validation, or other core skills deemed necessary by a partner employer*