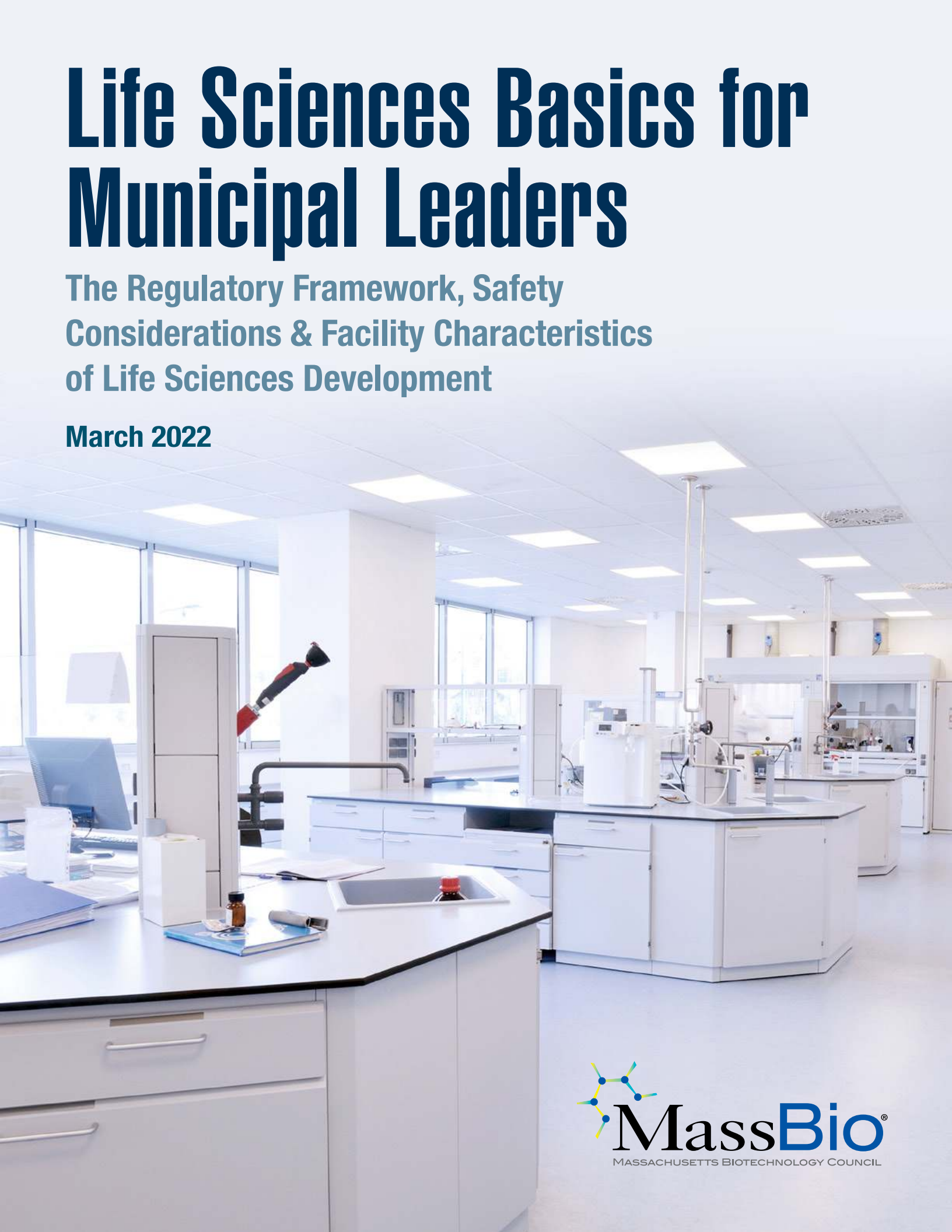
Life Sciences Basics for Municipal Leaders

The Regulatory Framework, Safety Considerations & Facility Characteristics of Life Sciences Development

March 2022



MassBio®
Massachusetts Biotechnology Council

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The Regulatory Framework, Safety Considerations & Facility Characteristics of Life Sciences Development

March 2022

MassBio would like to thank its Board of Directors' Economic Development Advisory Group for their guidance through the development of this resource as well as the following members of the MassBio community; The Town of Burlington, Berkeley Investments, and Erland Construction.

Welcome from MassBio's Executive Leadership

Massachusetts is home to leading academic medical centers, universities, early and emerging biotech companies, 18 of the top 20 global biopharma companies and strong investors. Combined with an immense talent pool and a unique partnership with government, Massachusetts is the best place in the world for the biotech industry.

Over the last fifteen years, Massachusetts has seen 95% growth in employment to over 84,000 people working in the biopharmaceutical industry.This coincides with the significant growth in the number of biotech companies launching and scaling across the state. This growth has only been possible alongside a substantial increase in laboratory space in Cambridge, Boston, and many other regional clusters. Over 21.6 million square feet of lab space has been built across Massachusetts over the last 10 years, an increase of 117% to a total of more than 40 million square feet. During this period, we have seen the successful growth of new clusters in places like Waltham, Lexington, Watertown, and Woburn. And many more are on the way up in places like Somerville, Burlington, Beverly, and Norwood.

With estimates of an additional 20 million square feet of new lab and biomanufacturing space opening in the coming years, MassBio sees significant opportunity for municipalities to develop their own biotech mini clusters.The goal of this document is to help community officials within Massachusetts better understand the biotechnology industry, how biotech facilities operate, and what leaders can do to best position their community for successful biotech development.

As a trade association representing over 1,500 member companies across the life sciences in Massachusetts and beyond, MassBio welcomes the opportunity to work with you to help your community best position itself for attracting and growing a life sciences cluster. The benefits of these developments are immense for communities and its residents. Please don't hesitate to reach out to us for further discussion.

Sincerely,

Joe Boncore, CEO, MassBio

Kendalle Burlin O'Connell, President & COO, MassBio

Benefits of Lab and Biomanufacturing Facilities to Host Communities

These modern and active facilities provide an excellent addition to diversify a municipality's tax base, bring new economic opportunity to residents, and invigorate local businesses. As we saw in places like Kendall Square or Watertown, when lab development takes place, restaurants, retail, and housing follow. When biopharma facilities open, foot traffic in the neighborhood increases, positively impacting small businesses and restaurants. With the recent economic downturn, the large-scale shift to remote or hybrid work schedules, new lab and biomanufacturing facilities, where most employees must work in-person, can bring new and welcome economic vitality to a community.

While many typically think of life sciences jobs as requiring a PhD, the reality is that many of the jobs only require a four-year degree and some entry-level jobs, especially in biomanufacturing, individuals can begin fruitful career without a Bachelor's degree. On top of the direct jobs, the biotechnology industry's employment multiplier is among the highest in the Commonwealth. ■

Attracting Life Sciences Development To My Community

There is no one specific tactic that attracts a life sciences organization to a municipality. More than anything companies are looking for a municipal partner, a site that they can occupy in short order, and access to talent.

To help community leaders assess what they can do to attract life sciences development in their municipality, MassBio has developed a rating system to determine a municipality's readiness to host lab and biomanufacturing facilities based on the community's zoning practices and infrastructure capacity. BioReady® rates these communities in four tiers from Bronze to Platinum. Through these BioReady ratings, MassBio seeks to provide cities and towns a platform to effectively tell their stories to the life sciences industry that will ultimately help real estate developers and life sciences companies find the most favorable destinations to locate. There are currently 90 BioReady communities across the Commonwealth that have all made a commitment to hosting the life sciences industry. ■

BioReady Communities

Listed below are the qualifications a municipality must meet to qualify for each tier—a good guide for any municipality thinking about attracting any kind of life sciences development—from labs to biomanufacturing.

Bronze

Municipalities at this level feature:

- Municipal water and sewer available in commercial and industrial areas.
- Zoning allows for biotech laboratory and manufacturing uses by special permit.
- Identified point of contact in town/city hall to assist biotech projects.

Silver

Municipalities at this level feature Bronze Criteria, plus:

- Municipality allows biotech laboratory and manufacturing uses by right.
- Has identified buildings and/or land sites for biotechnology uses in municipal plans.

AND 2 of the following 4:

- Municipality convenes site plan review meetings, bringing together all pertinent departments, to provide an overview of the local approvals process for significant commercial and industrial projects.
- Has land sites and/or buildings included in MassEconReadyMass100
- Community has identified Priority Development Sites per Chapter 43D.
- Municipality has a site designated as a Massachusetts Growth District.

BioReady Communities *continued*

Gold

Municipalities at this level feature Silver Criteria, plus:

- Municipality has sites or buildings pre-permitted for biotechnology laboratory or manufacturing use.

OR

- Municipality has existing buildings in which biotech laboratory or manufacturing activities are taking place.

Platinum

Municipalities at this level feature Gold Criteria plus:

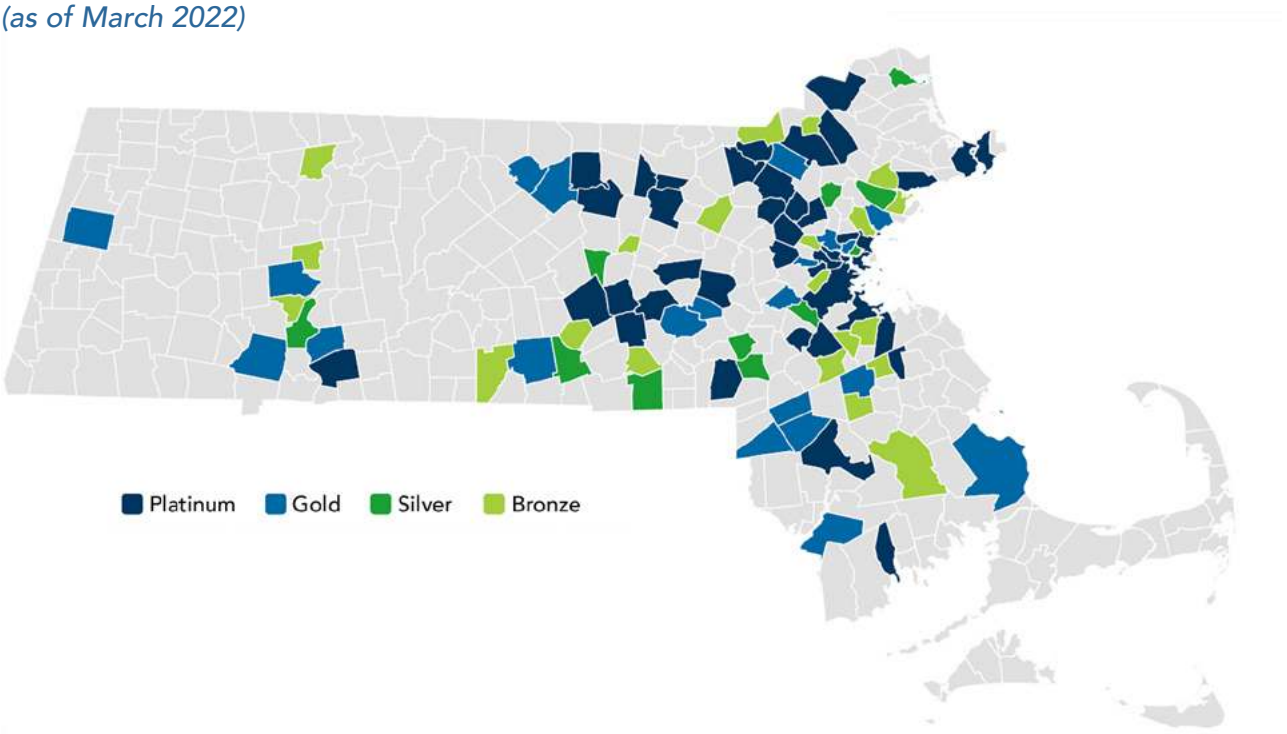
- Municipality's Board of Health has adopted the National Institutes of Health guidelines on rDNA activity as part of its regulations.
- Municipality includes a building or buildings that are already permitted for biotech uses and have 20,000 square feet or more of available space for biotech uses.

OR

- Municipality has a shovel-ready, pre-permitted land site with completed MEPA review and municipal water and sewer capacity to meet additional demand.

Massachusetts Bioready® Map

(as of March 2022)



General Characteristics of Life Sciences Facilities

From the building exterior, most life sciences facilities look similar to other commercial buildings. The most visible differences relate to additional ventilation and air purification systems which may require additional equipment on the building roof. Inside of the building, most facilities have a greater than average floor-to-ceiling height to accommodate additional heating, air conditioning, ventilation, and other utility requirements. For many reasons, these facilities are typically not high rises.

Facilities differ in size based on the size and stage of the company. Labs can range from 1,000 SF (smaller within an incubator) to upwards of 1m SF. In Massachusetts, most labs are in the 25,000 to 50,000 SF range. Manufacturing sites locally are typically between 50,000 and 200,000 SF including the office and lab space connected to them. They will also need loading docks and significantly higher ceilings.

Biotechnology facilities are generally segregated by functional activity between administration, general building support, laboratory, production, and laboratory/production support. The administration and general building support functions are consistent with other office buildings including office areas, conference rooms, corridors, elevators and cafeterias.

Laboratory units generally combine work benches, biological safety cabinets, chemical fume hoods and freestanding equipment. In addition, there are associated laboratory rooms for larger lab equipment, special instruments, data processing, glassware washing, solution and media preparation, sample processing/distribution, machine shops, electronic shops, darkrooms, microscopy rooms, and rooms for storage of supplies and chemicals. There are also environmentally controlled rooms for refrigeration and incubation.

Production and manufacturing areas are generally larger versions of laboratories. They are "clean rooms" designed to control the environment in order to protect biological processes and products from contamination. The air supply is typically HEPA (high efficiency particulate aerosol) filtered to prevent contamination of the products from airborne microorganisms found in normal outside air. Employees working in the area are required to wear special clothing, such as gowns and gloves, to provide a protective barrier between them and the biological processes and products.

Mechanical systems associated with heating, ventilation, and air conditioning (HVAC) are extremely important and address interior comfort, energy conservation and the protection of biological processes from normal room contaminants. Special systems are installed to highly purify domestic water for use in biological processes. Animal research facilities, when necessary, have separate HVAC systems to maintain the environment needed for the proper care of animals. Facilities generally have standby emergency generators to provide power to critical areas and equipment in the event of a power failure or brownout. ■

Biotechnology is Highly Regulated and Safe

Laboratories involved in biologic research and testing must conform to rigid regulations. In 2020, the U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health published the 6th Edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL).

The BMBL has become the code of practice for biosafety. Scientists practice biosafety in laboratories to safely and effectively study biological processes. State-of-the-art labs are designed not only to protect researchers from possible contamination, but also to prevent any microorganisms from entering the environment.

In the 37+ year history of biotechnology in Massachusetts the industry has a strong track record for safety. Regulations, controls, good laboratory practices, and laborious documentation of research all play a role in these high standards. Additionally, many of the organisms in use cannot survive outside of the controlled environments of the laboratories. Laboratory scientists and technicians are hired because of their mastery of good research practices. Their success as researchers is based upon their ability to apply these good practices in the research they conduct and laboriously record in full detail every working day. The ramifications for a research firm not to follow regulations governing biosafety are severe. Research firms not following sound laboratory practices and the regulations that control the industry would lose their standing with governing authorities such as the FDA and NIH, as well as their sources of government, venture, and corporate funding. Without such funding, no biotechnology company could operate.

Facilities are categorized on their respective Biosafety Levels (BSLs) ranging from the lowest risk of BSL-1 through the highest of BSL-4. 95% of all labs are BSL-1 or BSL-2. In these cases, the safety precautions are to protect the lab from human exposure as opposed to the inverse. Some towns have limited the levels of BSLs that can be located within the municipality. ■

What Can a Municipality Do to Properly Regulate Biotechnology Activity?

What many communities have done is to develop a by-law, regulation or ordinance based on current NIH guidelines. The simplest process for such regulation is the adoption of the NIH Guidelines as part of the local Board of Health's regulations. This regulation requires companies to register with the Board, giving assurance that its operations will follow NIH guidelines. These regulations allow the community and the commercial entity to understand what types of activities will be allowed in the locality. The community may choose to adopt the NIH guidelines as a whole as local ordinance or adopt specific regulations which may include simply the formation of an Institutional Biosafety Committee, which provide a role for the community in the oversight of laboratory activities, with an emphasis on biosafety. Here are the most current NIH Guidelines.

As the biotechnology industry has grown in Massachusetts and as it has been recognized as a highly regulated and safety-conscious industry, the trend in community regulations has been to have less-complex regulations as the biotech industry and the broader scientific field have shown rDNA technology to be very low risk both to employees and to the broader community. Additional requirements, such as special permits, ordinances, or regulatory committees, will create an atmosphere which discourages biotechnology companies from settling in a community. The NIH guidelines, together with other safety and environmental regulations, serve and protect the community from any potential risks from biotechnology laboratory and manufacturing operations, while creating an atmosphere that that welcomes biotechnology facility projects. ■

Frequently Asked Questions

Q In what areas are biotech companies doing research?

Massachusetts biotechnology companies are focused on cutting edge research for all types of human diseases. Massachusetts is home to some of the most innovative research in the world.

Q Are dangerous microorganisms or genetic material released into the water or air?

No. Biotech companies operate under strict federal, state, and local guidelines in handling hazardous materials. Any pathogenic, infectious, or otherwise hazardous microorganisms or genetic material is rendered harmless before being released into the environment.

Q Who monitors biotechnology companies to ensure they are in compliance?

Biotechnology companies are subject to a range of federal, state, and local regulations including local community representatives involved in the industry project reviews.

Q If the work is safe, why do employees wear special clothing?

Protective clothing is provided to protect the products and biological processes from foreign substances, such as human contamination, within the controlled environment. Naturally occurring microorganisms when introduced into that environment could interfere, delay or ruin the biological process. Such clothing also protects employees in these settings.

Q Are animals used in biotechnology research? How are they handled?

Animals, primarily rodents such as rats, are a necessary component of scientific research. The FDA requires animal research and testing on all drugs and medical devices before they are tested in humans. In handling animals, all companies are under the jurisdiction of the U.S. Department of Agriculture and are required to conform to the standards of the Animal Welfare Act.

Q Can people visit biotechnology companies to see what is going on?

Most companies welcome visitors at planned and controlled times and have programs with the local educational community to provide information and promote science education. In addition, Institutional Biosafety Committees, formed for those companies involved in recombinant DNA technology, include local representatives often chosen by the local Board of Health who visit companies on a regular basis.

Q What can my municipality do to attract biotech companies?

More than anything, companies are looking for a municipal partner in the community that they decide to grow up. Anything that a municipality can do to expedite speed to occupancy will be hugely beneficial to the company.

About MassBio

MassBio is a not-for-profit organization

founded in 1985 that represents and provides services and support for the #1 life sciences cluster in the world.

MassBio's mission is to advance Massachusetts' leadership in the life sciences to grow the industry, add value to the healthcare system, and improve patient lives.

We represent the premier global life sciences and healthcare hub, with 1,500+ members dedicated to preventing, treating, and curing diseases through transformative science and technology that brings value and hope to patients. MassBio is also committed to helping communities, local and state governments and regulatory agencies understand biotechnology, its realized and potential contributions to society, the benefits to the local economy, and the specific needs of the industry.

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Appendix

Regulations Associated with Biotechnology Activities and Operations

Biotechnology facilities are highly regulated and monitored. Below is a list of potential permits, approvals and reports necessary for the approval, construction, and operations of a biotech facility. Certain planning and code requirements, applicable to any property development—such as plumbing or building permits, or site assignments—are not included in the table. The table focuses on activities or operations that may trigger environmental, health, and safety related permits, licenses, registrations, or reports. In addition to the below, many municipalities chose to establish an Institutional Biosafety Committee (as defined by the National Institutes for Health) through their Board of Health or otherwise.

Regulatory Authorities Guide

Federal

EPA – U.S. Environmental Protection Agency

DEA – Drug Enforcement Agency

NRC – U.S. Nuclear Regulatory Commission

State

DEP – Department of Environmental Protection
DFS – Department of Fire Services
DPH – Department of Public Health
DPS – Department of Public Safety
SERC – State Emergency Response Commission

Municipal

BOH – Board of Health
Publicly Owned Treatment Works (e.g., MWRA)
Fire Department
Inspectional Department
Planning or Zoning Board
Water Supplier

Potential regulatory permits, submittals, or approvals applicable to biotechnology facilities.

Multiple requirements may apply.

Activity or Operation	Registration	Permit, License or Approval	Self-Certification or Report	Regulations
Air Emissions (including boiler/furnace installations & operations)	DEP	USEPA, DEP	DEP	√
Boiler Operator Certification		DPS		√
Controlled Substances		USDEA, DPH		√
Cross Connection (Water)		DEP, Local		√
Emergency Generator	DEP		DEP	√
Emergency Planning	USEPA, USHHS		SERC, Local	√
Ethyl Alcohol Usage		USTTB		√
Flammable and Combustible Materials		Local		√ (DFS)
Groundwater Discharge/Water Reuse		DEP	DEP	√
Hazardous Waste	EPA, DEP	DEP (for treatment)	EPA (LQGs)	√
Industrial Sewer Discharge		DEP, Local	DEP, Local	√
Laboratory (R & D) Activities		BOH		√ (OSHA)
Laboratory Animal Care and Use		USDA, DPH, BOH	USDA	√
Life Safety (Fire Alarms, Security)		Local		√ (DFS)
Medical or Biological Waste				√ DPH

Noise (e.g., rooftop mechanicals)				√ DEP, BOH
Radioactive (Nuclear) Materials		DPH		√
Storm water		EPA, DEP	EPA, DEP	√
Surface Water Discharge		EPA, DEP	EPA, DEP	√
Tanks	DEP, Local	DEP		√
Toxic Chemical Usage or Byproducts – Large Manufacturers (i.e., TURA)			DEP	√
Water Supply and Connection		DEP, Local	DEP, Local	√

Laboratory & Manufacturing Plant Physical Requirements

The charts which follow identify facility requirements applicable to the five typical biopharmaceutical facilities:

1. Basic Research facility
2. Process Development facility
3. Pilot Production facility
4. Manufacturing facility

The chart titled Facility Space Allocation is designed to show the percentage of space allocated to different functional areas within the facility.This tool is designed to assist municipalities, citizens and town officials, as well as developers and biotechnology professionals in providing a guideline of engineering and architectural requirements that are commonly seen in such facilities.This tool is not designed to identify all relevant and applicable requirements.

	Basic Research Facility	Process Development Facility	Pilot Manufacturing	Manufacturing
Hours of Operation	Typical business hours	Typical business hours	24 hrs/day, 7 days/week	24 hrs/day, 7 days/week
Floor to floor heights	14-18 ft	14-18 ft	18-35 ft	20-40 ft
Electrical	12KV	12KV	15KV	25KV with redundant supply
Water	8,000-20,000 GPD	20,000 GPD	2,400 GPH per 1,000 SF	Varies. Greater than pilot facility.
Sewer	Some pretreatment. Use of Neutralization tanks	Pretreatment using neutralization tanks	Adequate public sewer capacity.	Adequate public sewer capacity.
Gas	Required	Required	Higher volume than research of process facilities	High volume

Basic Research Facility/Lab Base Building Considerations

FACILITY SPACE ALLOCATION		TYPICAL RANGES	ADDITIONAL COMMENTS
	Density	350-500 RSF per lab employee	
	Hours of operation	9AM to 5PM	Facility must have 24-hour access to utilities
DIMENSIONS			
Area	Footprint Minimum footprint	30,000 to 60,000 SF 10,000 to 20,000 SF	
Height	Floor-to-floor	14-15 ft for new construction 12+ ft for conversion	Note: dependent on building structure type.
	Exterior building height	Minimum height 24-28 ft	Applicable for single story building, including roof top mechanicals.
STRUCTURAL DESCRIPTION			
Floor Load	Structural loading (live loads)	100 to 250 PSF	100 PSF to 150 PSF in laboratory areas. Up to 250 PSF in MEP and Mechanical Penthouse areas
	Vibration sensitivity	500 to 2,000 micro inch per second	500 micro inch per second for high power (up to 30,000x) 2,000 micro inch per second (at natural building frequency) for medium power (up to 400x magnification)
Column Layout	Structural grid	20-22 ft by 30 ft	Note: This is optimum size for average lab module.
BUILDING UTILITIES			
Electrical	Emergency and back-up generator	Required for life safety only.	Note: When used for life safety for Base Building, typically use an alternate onsite fuel source. For tenant back-up power, typically use gas-fired generators.
	Electrical service	12-16 Watts/ USF lab 6-12 Watts/USF office	
	Steam	Not applicable	
	HVAC	1.75-2.0 CFM/USF standard lab 0.25/USF office	
SITE UTILITIES			
	Water	8,000 to 20,000 GPD	Note: Dependent on type of facility
	Sewer	8,000 to 20,000 GPD	Typically some pre-treatment equipment such as neutralization tanks
	Gas	Natural gas required	For lab use: low pressure used. For building heating: moderate pressure and higher volumes. Some labs limit bench top gas to botted units as safety precautions.
SITE CIRCULATION			
Future Needs	Expansion Space	Preferable	Desirable for growth.
	Deliver needs and access	Roadways	Typical commercial or light industrial access for loading docks. Moderate truck activity for laboratory deliveries.
	Exterior security	Limited access to lab areas and tenant demarcations. Building access controlled.	

Process Development Facility

FACILITY SPACE ALLOCATION		TYPICAL RANGES	ADDITIONAL COMMENTS
	Density	2-3 employees for over 1,000 SF	
	Hours of operation	9AM to 5PM	Facility must have 24-hour access and use of facilities
DIMENSIONS			
Area	Footprint Minimum footprint	10,000 to 20,000 SF 10,000 to 20,000 SF	
Height	Floor-to-floor	14-18 ft	Note: dependent on building structure type.
	Exterior building height	Minimum height 24-28 ft	Applicable for single story building, including roof top mechanicals.
STRUCTURAL DESCRIPTION			
Floor Load	Structural loading (live loads)	100 to 250 PSF	100 PSF to 150 PSF in laboratory areas. Up to 250 PSF in MEP and Mechanical Penthouse areas.
	Vibration sensitivity	500 to 2,000 micro inch per second	500 micro inch per second for high power (up to 30,000x) 2,000 micro inch per second (at natural building frequency) for medium power (up to 400x magnification)
Column Layout	Structural grid	20-22 ft by 30 ft	Note: This is optimum size for average lab module, similar to Basic Research Facility
BUILDING UTILITIES			
Electrical	Emergency and back-up generator	Required	
	Electrical service	12 KV Primary	Typically 208/110V with usage in the 25-40 Watt/SF range
	Steam	16,000 lbs/hr	Such facilities typically use equipment that generates its own steam or a small electrical generator
	HVAC	2.0-3.0 CFM/SF	
SITE UTILITIES			
	Water	20,000 GPD	
	Sewer	20,000 GPD	Typically some pre-treatment equipment such as neutralization tanks
	Gas	Natural gas required	For lab use: low pressure used. For building heating: moderate pressure and higher volumes. Some labs limit bench top gas to botted units as safety precautions.
SITE CIRCULATION			
Future Needs	Expansion Space	Preferable	Desirable for growth.
	Deliver needs and access	Roadways	Typical commercial or light industrial access for loading docks. Moderate truck activity for laboratory deliveries.
	Exterior security	Limited access to lab areas and tenant demarcations. Building access controlled. Access to lab areas must comply with FDA.	

Pilot Biopharmaceutical Manufacturing Facility

FACILITY SPACE ALLOCATION		TYPICAL RANGES	ADDITIONAL COMMENTS
	Density	2 employees per 1,000 sq ft	
	Hours of operation	Operation is 24 hrs/day, 7 days/week	
DIMENSIONS			
Area	Footprint Minimum footprint	10,000 to 35,000 SF 10,000 SF	
Height	Floor-to-floor	18-35+ ft	Clear height production requirements 17-22 ft
	Exterior building height	Minimum height 28-35 ft	Applicable for single story building, including roof top mechanicals.
STRUCTURAL DESCRIPTION			
Floor Load	Structural loading (live loads)	100 to 250 PSF	100 PSF to 150 PSF in laboratory areas. Up to 250 PSF in MEP and Mechanical Penthouse areas, and possibly process development areas
	Vibration sensitivity	Varies	May have highly sensitive equipment. This type of facility is typically not as stringent as a lab or process development facility.
Column Layout	Structural grid	15-20 ft clear space between columns	Open floor plan is preferred for this type of facility. Interior access for large equipment is required.
BUILDING UTILITIES			
Electrical	Emergency and back-up generator	Required	
	Electrical service	15 KV Primary	
	Steam	16,000 lbs/hr	Typical range: 0.25 lbs/hr/SF. This may be dependent on the manufacturing process.
	HVAC	2.0 CFM/USF standard lab	Clean room space requires 25 or more air changes per hour.
SITE UTILITIES			
	Water	Varies with process	Typical range: 0.35 GPH/SF peak
	Sewer	Calculation should be based on supply minus volume of water that goes into product. Public sewer with adequate capacity is required. Discharges typically require kill system and pH pretreatment.	
	Gas	Natural gas required	Typically higher volume than in Basic Research and Process Development facilities
SITE CIRCULATION			
Future Needs	Expansion Space	Recommended	Desirable for growth.
	Deliver needs and access	Truck and tanker access, as well as airport and highway access is preferable	Typical commercial or light industrial access for loading docks. Moderate truck activity for laboratory deliveries. Truck and crane access for large equipment deliveries. Facility may require bulk gas and tank storage.
	Exterior security	Limited access to lab areas and tenant demarcations. Building access controlled. Access to comply with cGMP guidelines.	

Biopharmaceutical Manufacturing Facility

FACILITY SPACE ALLOCATION		TYPICAL RANGES	ADDITIONAL COMMENTS
	Density	1 employee per 1,000 sq ft	
	Hours of operation	Operation is 24 hrs/day, 7 days/week	
DIMENSIONS			
Area	Footprint Minimum footprint	50,000 to 150,000 SF Varies	
Height	Floor-to-floor	20-40 ft	Clear height production requirements 17-22 ft
	Exterior building height	30-65 ft (single story building)	Transport overload limits equipment to about 30 ft in height maximum. Building height of 40 ft is sufficient for process and warehouse. Total building height is 65 ft, including mechanical space above.
STRUCTURAL DESCRIPTION			
Floor Load	Structural loading (live loads)	100 to 250 PSF	100 PSF to 150 PSF in laboratory areas. 250 PSF in manufacturing areas. Warehouse – slab on grade, spine 150 PSF.
	Vibration sensitivity	Varies – equipment specific	May have highly sensitive equipment in specialized suites.
Column Layout	Structural grid	Varies due to equipment size	Open floor plan is preferred for this type of facility. Building interior must accommodate large (10 ft by 30 ft) equipment, with access on multiple floors of the facility.
BUILDING UTILITIES			
Electrical	Emergency and back-up generator	Required	Minimum range: 5KW-10KW/SF, however, is dependent on the process. Varies per critical equipment requirements.
	Electrical service	25 KV Primary	Facility may have dual underground feeders from separate substation.
	Steam	Varies per process requirements	
	HVAC	Greater than 2CFM/SF	Clean room space requires 25 or more air changes per hour.
SITE UTILITIES			
	Water	Varies with process	Greater than Pilot Manufacturing facility.
	Sewer	Calculation should be based on supply minus volume of water that goes into product. Public sewer with adequate capacity is required. Discharges typically require kill system and pH pretreatment.	
	Gas	Natural gas required	Typically high volume.
SITE CIRCULATION			
Future Needs	Expansion Space	Recommended	Desirable for growth.
	Deliver needs and access	Truck and tanker access, as well as airport and highway access is preferable	Typical commercial or light industrial access for loading docks. Truck and crane access for large equipment deliveries. Facility may require bulk gas and tank storage. Multiple access points required.
	Exterior security	Site access control is required.	Controlled access required for cGMP regulated facilities.

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