Roadmap for BioFabUSA Education and Workforce Development 2018-2019

Developed by

a program of armi

biofabusa

Contents

Executive Summary

The goal of the BioFabUSA program is to enable the scalable, consistent, and cost-effective manufacturing of tissue engineered medical products (TEMPs) by:

- Removing existing hurdles to reproducible tissue biomanufacturing.
- Producing modular and scalable GMP-compliant manufacturing processes and integrated technologies.
- Developing and standardizing manufacturing practices across the field.
- Closing the skills gap in tissue and organ manufacturing through accessible training opportunities from "K to gray", and disseminating knowledge and technologies to enable continued innovation.

Essential targets for Education and Workforce Development efforts by ARMI | BioFabUSA:

- Post-high school learners in community college, veterans, certification-seekers, returnees to the workforce, current technical staff, biotechnical laboratory employees outside of traditional four-year colleges, and non-engineers in the TEMP field
- Science and engineering bachelor's degree recipients requiring interdisciplinary training and experience
- Early STEM learners aspiring to careers in TEMP manufacturing
- Continuing education for industry and academia in regulatory pathways for TEMPs

The following activities have been identified as short-term priorities for the industry:

- Generate broad awareness of and interest in tissue engineering to lay a foundation for future workforce growth:
    - Establish a central resource for K-12 instructional materials and provide mechanisms for students and teachers to experience biofabrication activities
    - Align current educational frameworks (e.g., Next Generation Science Standards (NGSS), Common Core, and Career and Technical Education (CTE)) with biofabrication skills
    - Engage younger student audiences in exploring biofabrication careers
    - Engage undergraduate and graduate audiences in exploring biofabrication careers

- Align biofabrication position requirements and skills while developing education, training, and certifications across the industry to allow for less specialized and more widely accessible support for the biofabrication workforce:
    - Collect information on education, training, and careers in tissue engineered medical products
    - Align biofabrication jobs with relevant skills and educational and training assets within BioFabUSA by refining the competency pyramid annually
    - Support online and hybrid learning to address technical knowledge gaps in order to reach learners across the country
    - Provide opportunities for educational and industry members to collaborate in developing and enhancing curricula for biofabrication needs
    - Assess the impact of stackable credentials, certificates, and badges at the various job levels within the industry
    - Establish regulatory, standards, and legal training curriculum needs at all levels and positions

Purpose and Scope

Over the last several decades, there has been significant scientific progress in the field of tissue engineering. However, only a very small percentage of this progress has translated into marketed tissue engineered medical products (TEMPs). The lack of commercially available TEMPs is largely attributed to the challenges of manufacturing therapies consistently, cost-effectively, and at scale. The Advanced Regenerative Manufacturing Institute (ARMI), an industry-led public private partnership, was created to address these challenges through the Department of Defense (DoD)-funded BioFabUSA program. The institute has created a collaborative community that includes TEMP developers and manufacturing solution suppliers from commercial firms and academia, who conduct interdisciplinary, advanced manufacturing research and development (R&D). This R&D activity aims to develop common, modular manufacturing platforms and associated processes, standards, and know-how to de-risk and lower the cost of developing and executing robust manufacturing for any TEMP.

To accomplish this mission, BioFabUSA is focused on the following goals aimed toward achieving scalable, consistent, cost-effective manufacturing of Tissue Engineered Medical Products:

- ❖ Remove existing hurdles to reproducible TEMP biomanufacturing
- ❖ Produce modular and scalable good manufacturing practice (GMP)-compliant manufacturing processes and integrated technologies
- ❖ Develop and standardize manufacturing practices across the field
- ❖ Close the skills gap in tissue and organ manufacturing through accessible training opportunities from “K to gray”
- ❖ Disseminate knowledge and technologies to enable continued innovation

This roadmap describes the information collected from ARMI | BioFabUSA and its members, and details priorities for BioFabUSA’s Education and Workforce activities. A separate Technical Roadmap is available through ARMI | BioFabUSA that details the advanced research and development tasks related to the technical goals of the BioFabUSA program, and is the companion document to this.

A Look to the Future Workforce

The future workforce is comprised of people able to work within a multidisciplinary team of engineers, automation experts, biologists, and technicians to make a difference in the world by reducing the wait times for organ and tissue transplants and by providing medical solutions for those impacted by degenerative diseases and traumatic injuries.

The required skillset for the emerging industry of tissue engineered medical products will evolve as technologies and manufacturing platforms are implemented for product commercialization. The need for innovations by highly trained scientists and engineers will remain, as the field develops new solutions and technologies. With the maturation of manufacturing capabilities, the need for highly skilled technicians will increase.

BioFabUSA has mapped available educational assets to identify gaps in current education and training curricula. The organization seeks to leverage the information to provide career pathway guides and encourage early-learners to pursue career opportunities in this field. Mechanisms must be in place to allow for career exploration and real-world experience.

The TEMP workforce must draw upon a range of skills that reflect the integrated nature of the industry, where technology advances bridge cell biology, engineering, automation, regulatory science, and data analytics. Each of the "fields" has its own vocabulary, jargon, and definition of terms. A major unmet need is creation of a dictionary or "glossary" that could foster cross-communication. This need does not solely rest in the realm of EWD, but requires the coordinated ecosystem efforts to insure academia and industry communicate effectively.

As technologies and practices evolve and standardize, workforce training must adapt and integrate the necessary skills into education and training at all levels.

BioFabUSA recognized the necessity of engaging stakeholders to develop this roadmap. Input was derived from in-person round table discussions, data from a formal needs-analysis survey, a working pathways summit, and courses intended to improve biofabrication skills. These data were the result of projects funded by ARMI | BioFabUSA in 2017-2018.

BioFabUSA believes that the EWD roadmap helps accomplish the vision of the regenerative medicine/tissue engineering community to improve the health and life of patients.

Tissue Engineered Medical Product Industry Landscape

The tissue engineering industry is primed for rapid expansion. With very few products on the market, the potential lies in the many preclinical products and technologies. There are more than 100 companies with engineered tissues in development, and hundreds more engineered tissues are under development in academic settings. These engineered tissues address a wide variety of medical needs, many in soft tissue and cartilage. The development of microvasculature remains a significant hurdle to the production of three dimensional vascularized tissues. An even larger number of companies are focused on adjacent technologies within the supply chain, ranging from cell line development to the cryopreservation of engineered tissues.

Based on research conducted by ARMI | BioFabUSA, the industry has experienced significant growth in recent years. The number of tissue engineering companies nearly doubled from 2005-2015, signifying the proliferation of employment and market opportunities. The increase is a result of advancements made in cell therapy such as 3D culture and reliable cell line development. Advancements in electrospinning, additive manufacturing, and decellularization have resulted in an increase in organizations supplying scaffolds for tissue culture.

While the number of organizations within the TEMP industry is increasing, approximately half of the companies are comprised of 20 employees or fewer. Data from an industry survey by Rutgers/NJ Center for Biomaterials in 2018 indicate that the companies in this industry have open positions and also plan to expand their workforce in the near future.

Conclusion

There are two principle needs for the future: a trained technical workforce and flexible, multidisciplinary science and engineering innovators.

The skills required for the emerging industry of tissue engineered medical products will evolve as technologies and manufacturing platforms are implemented for product commercialization. Highly trained scientists and engineers will be needed to develop new solutions and technologies. The education of graduate and postdoctoral scientists and engineers is ably handled by existing universities, but enabling improved better communication between companies and academic/training institutions as well as between disciplines, will allow for the development of the multidisciplinary skills required in this industry.

ARMI | BioFabUSA has identified the following workforce groups for TEMPs which are the principal targets for Education and Workforce Development efforts by ARMI | BioFabUSA:

- Post-high school learners in community college, veterans, certification-seekers, returnees to the workforce, current technical staff, biotechnical laboratory employees requiring flexible and innovative learning modalities outside of traditional four-year colleges
- Science and Engineering bachelor's degree recipients requiring interdisciplinary training and experience
- Early STEM learners seeking inspiration and motivation for careers in manufacturing of advanced therapies

Current Skills Needed in the TEMP Field

The interdisciplinary nature of the field necessitates a wide variety of skills. The skills identified from roadmapping activities are not specific to a particular job, but rather to the field as a whole. The chart below identifies the most commonly identified skills.

Soft Skills

Soft skills include oral and written communication, organization, responsibility, integrity, teamwork, collaboration, and timeliness. Being inquisitive and methodical, with a propensity for problem solving are desired workforce traits. The issue of soft skills was repeatedly raised in roadmapping workgroups, and consensus suggested that teachers, instructors, and professors should be mindful to integrate the value of these behaviors in their courses, despite the difficulty of specific training for these skills. These skills were noted repeatedly but are not found on the chart below, as they are common to all industries; this roadmap seeks to address gaps specific to the TEMP fields.

BIOFABRICATION SKILLS	High[1]	Med	Low
Aseptic Technique			
Regulatory			
Quality Assurance / Quality Control / Validation			
Process Development & Management / Quality by Design (QbD)			
Metrology / Standards			
Microscopy / Microdissection / Imaging			
Data Management / Analysis / Statistics			
Automation / Robotics			
Basic Cell Culture / Tissue Culture			
Engineering			
Biomaterials Properties & Fabrication			
cGMP / GLP / SOP / Documentation			
Biology / Cell Biology / Physiology			

BIOFABRICATION SKILLS	High[1]	Med	Low
Computer Programing			
Clinical / Preclinical			
Legal Expertise / Intellectual Property			
Histology			
Animal handling			
Basic Manufacturing / Supply Chain			

[1] Priority of Skill

Aseptic Technique

Aseptic technique, safety, and lab training are commonly provided in laboratory science courses. Some industry members note that they conduct additional aseptic training at significant cost. Environmental certifications are dependent upon the intended use of the space. Isolation of cells can require training in aseptic technique as well as an understanding of the regulatory context for that requirement. The specific training for Biosafety Level 2 would likely be covered in an aseptic technique module and during cell and tissue culture courses. Specific equipment for cell culture, such as bioreactors and flow cytometers should be operated under aseptic technique for effective use. Respondents questioned whether the level of aseptic technique training provided in cell and tissue courses is sufficient for industry positions. Specific descriptions of the positions and equipment requiring additional training for industry must be more clearly defined. While clean room skills are a current priority, the ARMI | BioFabUSA Technical roadmapping suggests a potential for manufacturing outside of the traditional clean room environment; requirements for training in this area will continue to be evaluated as industry practices mature.

Regulatory Knowledge

TEMP industry representatives at all levels of workforce participation – from company founders to engineers, product developers, and technicians – all require accurate comprehension of regulatory pathways. Shared regulatory knowledge allows teams to communicate more effectively and to work together to devise solutions. Additionally, stakeholders identified preclinical, clinical, legal, tissue procurement, and informed consent knowledge as a requirement for the next generation of technicians, especially as the manufacturing of tissues becomes a routine aspect of healthcare.

Other Skills Grouped by Relative Apparent Need

The remainder of the skills are grouped by functional area. Quality Control (QC), Quality Assurance (QA), and validation, (including the need for assay training and molecular biology skills that may be part of those processes) comprise the first group of skills

Microscopy was grouped with microdissection and imaging, but more information regarding job-specific microscopy training requirements must be explored.

Data management, analysis, and statistics were grouped as skills important for the field, and are understood to be common to many science positions.

In the 2017 and the 2018 Life Science Workforce Trends Report by The Coalition of State Bioscience Institutes (CSBI) (http://docs.wixstatic.com/ugd/dd6885_ea3d44ce3ef24e228ddc59a45b7f0563.pdf), data management and analysis were emphasized as needs. These skill sets are also applicable to automation, robotics, and computer programming, but should be more clearly defined for the TEMP field, where newer technologies increasingly rely on computational skills. It will be important to clarify the skillset required for specific jobs within the industry.

Skills such as process development and management, along with protocol design and optimization, point to an increased need for training in Quality by Design (QbD). The ARMI | BioFabUSA Technical Roadmap emphasizes the importance of QbD principles in manufacturing. Similarly, metrology is an expansive set of skills related to measurement, which includes not only optical measurements but also mechanical, physical, and analytical measurements. In addition to the accurate obtaining and analysis of these measurements, there is also a need to examine how measurements are reflected as product standards for manufacturing.

In the tissue manufacturing field, there is also a need for skills in current Good Manufacturing Practice (cGMP), Good Laboratory Practice (GLP), Standard Operating Procedures (SOP), and proper documentation of those processes. It is imperative that education and training remain up-to-date as both industry and regulatory requirements continue to evolve. The workforce is also benefitted by skills in basic manufacturing principles, project management, and supply chain management.

Additionally, both engineering and biology skills were noted as a general need. Math, chemistry, and physics for engineering, as well as biomaterials, material fabrication, and characterization were identified as important. Expansion of biological skills, including cell biology, physiology and histology, basic cell and tissue culture, and understanding of cell identity and differentiation are also important. The monitoring and testing of cells and tissue will be required, as well as Quality Assurance and Quality Control (QA/QC), and validation assays. Animal handling skills may be required for certain R&D positions, or those supporting preclinical testing of tissue-engineered products rather than the manufacturing of human tissue.

The discussion between academia and industry sets the stage for continued collaboration on identification of important skills.

Current Methods for Technical Skill Development

On-the-job training, often one-on-one, is the most common way employees gain the specific skills needed. Both lab-based coursework and internships/apprenticeships greatly contribute to training, offering both hands-on learning and real-world problem solving. Traditional academic and lecture-based courses provide information, but additional application of knowledge is needed. Many academic institutions are incorporating more experiential and project-based learning into their curricula, curriculum development can be further improved

through purposeful dialogs, such as advisory boards, meetings, and conferences. While internships and apprenticeships are providing students with exceptional learning experiences, there remains an insufficient number of opportunities. For smaller companies and academia, internships and training can prove to be more of a burden than a benefit due to the resources required for implementation.

Current Methods for Technical Skill Development	High[2]	Med	Low
On-the-job training			
Externships / Internships / Apprenticeships			
Small group workshops			
Online training			
Blended training (online with hands-on component)			
Professional society workshop			
Postgraduate education			
Other			

[2]Frequency of type of training

Online training, webinars, and workshops are available from academic and professional societies, offering field-specific training in a condensed format, often allowing attendance by individuals currently employed or with an otherwise restricted schedule. Online courses can be taken without the need to attend in person, but do not provide the hands-on component that many feel necessary. Courses which combine the accessibility of online learning with local, hands-on training provide a promising solution. Post-graduate education with a research component provides soft-skills and technical skills training, but an advanced degree may not be necessary for some jobs. Currently, the hiring of advanced-degree graduates for technician level positions is seen as problematic due to high turnover rates for those positions. As the manufacturing platform for TEMPs is developed by industry, the development of national training programs will be critical.

Other mechanisms for skills training are needed. Community colleges play a significant role in training for advanced manufacturing, and facilitate student pathways from Career and Technical Education (CTE), STEM, and Innovation Institute programs at the high school level, often with dual enrollment credit provided. Individualized training, managerial coaching, military veteran training, Manufacturing Extension Partnerships (MEP), career transition training programs, and sabbatical training for academics to work in industry or to start a spin out company play a role in training the future workforce. The preferred nature of training may vary depending on the geographic region.

There is a need for balance between providing curricula on a national scale and the hands-on experience critical to developing industry ready skills.

Effective Education and Training for the Technical Workforce

Effective education lies ultimately with training and the needs of the individual enrolled. Generally, the most effective education and training for TEMP skills requires both hands-on training and the integration of real-world issues into classroom material. The goal is to communicate the industry-needed skills to creators of educational curricula. Industry input suggests that optimal hands-on training is conducted in small groups or one-on-one, over only a couple of days. The preferred training location, however, was off-site, potentially to reduce the impact to the jobsite from loss of production time. Programs developed for skilled technicians at community colleges, as with other advanced manufacturing training, are likely to be well received by industry.

Other types of training with real-world and hands-on aspects include online and hybrid training, with the potential to incorporate an element of simulation to provide "real" experience without the need to invest in expensive equipment. Additionally, updating virtual training would be easier, faster, and less expensive than its real-world counterpart. Competency-based assessment provides evidence of acquired ability and has significance beyond a list of completed classroom courses. A disconnect exists between what competencies are achieved by a course, as well as what credit can be provided for a course based on competencies achieved outside of a classroom. This is particularly important for those in the workforce that wish to transition into the industry from military service or from other manufacturing industries. Linking competency- and classroom-based assessment with credentialing or similar documentation of experience could provide a mechanism to bridge the divide. Medical, clinical, and public health education acknowledge these types of training and experience.

Effective Education and Training for the Innovator Workforce

Postdoctoral and postgraduate academic institutions are providing advanced degree education in diverse areas contributing to the biofabrication field. There are opportunities to facilitate communication between companies and academia in order to ensure students and the workforce attain an appropriately industry-specific skillset needed to continue the use and development of the evolving technology. The integration of applied industry practices and procedures will provide insight to those considering careers in industry as opposed to an academic research pathway. The innovator workforce for tissue engineered medical products, nevertheless, requires a pipeline of highly interdisciplinary employees with hands-on experience and practiced communication skills.

Remaining Skillset Gaps

Based on the roadmapping activities over years 1 and 2, it is clear that regulatory, standards, legal, and clinical information, as well as scale-up, process optimization, and Quality by Design education, are highly desired industry skills, in addition to cross-disciplinary training for where gaps remain. Once these manufacturing skillset gaps are addressed, academia and other training outlets can begin to bolster the workforce pipeline with candidates well-suited for the unique dynamics of the TEMP industry.

Remaining Skillset Gaps	High[3]	Med	Low
Regulatory / Standards / Legal / Clinical Information			
Process optimization / Scale-up / Quality by Design (QbD) training			
Interdisciplinary skills			
Project Management			
Data analysis/ Statistics			
Other			

[3]Level of perceived need for skill

Additional skill gaps were noted with regard to experiential learning, data analysis and statistics, and automation. While mechanisms currently exist to foster these skills, there is an increasing need to improve their accessibility. It is interesting to note the need for skills related to the transition from academic to industry settings, specifically the incorporation of business aspects and goals. Additional study is required to determine which TEMP industry positions would benefit most from these skills, and what level or models of business courses would be most applicable.

Defining Existing Barriers to Education and Training

The most significant barriers to training lie in the lack of a sufficient workforce pipeline and the need for more academic-industry communication and partnerships. As an emerging industry, there is relatively little information available for the prospective workforce, especially for young students who are making decisions about career pathways as early as middle school or younger. There is also a barrier to accessing veterans who may be looking to transition from active service into a civilian career and for those seeking training to enter the field from a different career pathway. By helping to define resources for those seeking to get more information or to enter the industry, we will be able to increase the available workforce.

Evolving technologies within the biofabrication field pose challenges in establishing educational curricula and certifications, especially with limited industry input and access to updated equipment. Industry internships and apprenticeships provide opportunities to gain valuable experience, but even an increase in opportunities can only remedy some of the issues.

While other concerns were noted (e.g., training costs, awareness of job availability, and the need to emphasize soft skills), it was clear that many of these barriers were linked to the need for communication among

stakeholders in devising an action plan. ARMI | BioFabUSA can play a significant role in convening stakeholders to facilitate these discussions and aid in the development of solutions.

How to Overcome the Barriers to Education and Training

The initial suggested strategies included an increase in academic and industry partnering, online/hybrid courses, internships, short courses, and certifications. Industry input is essential for informing the design of the desired skillset, and for highlighting current production technologies. Establishing competency models specific to tissue manufacturing is necessary for continued education and workforce development. Competencies defined by job requirements set by industry will inform and better direct many of the suggested strategies.

Strengthening the educational pipeline via K-12 awareness will also require clearly defined competencies, especially as secondary schools are continuing to align in offering dual enrollment college credit for students. These competencies can aid in creating a penchant for lifelong learning – a perspective which benefits the emerging industry workforce through the ease of adapting new skills and potentially earning academic credit for skills learned on the job.

STRATEGIES TO OVERCOME BARRIERS TO WORKFORCE TRAINING	High[4]	Med	Low
Industry-academic partnering for curriculum / Online / Hybrid curriculum			
Increase pipeline K-12 for interest / Awareness / CTE			
Establish short courses / Certifications			
Increase internships / Project-based learning / Case study models			
Establish competency models			
Central location for finding training / Jobs			
Provide regulatory / Legal training			
Clinical exposure			
Leasable facilities for training (Core labs)			
Open access / Webinars / Modular			

[4] Priority of Need

With many educational efforts underway, a digital information hub can provide a central location for the BioFabUSA community to access workshops, webinars, online courses, training, and job postings. In the fall of 2017, ARMI | BioFabUSA researched the creation of a talent exchange to benefit both members – by posting their available positions – and non-members/the general public – to whom the postings would be visible.

Shortly after the Fall 2017 summit, the "Career Opportunities Exchange" posted several positions, including internships for undergraduates and high school students. While still in the beta stage, the Exchange has demonstrated value. As members provide feedback on their needs, the Career Opportunities Exchange will be enhanced.

Education and Workforce Development Action Plan

Based on the gaps, needs, and suggested strategies from members, the next steps for coordinated action are awareness, community outreach, and future workforce development.

ARMI | BioFabUSA will act as a hub of resources for its members, and will communicate with the larger community to bring heightened awareness to the field.

Future development activities are bracketed within subcategories which combine the need to communicate to the general public and to increase the pipeline with a "K to gray" strategy that ensures that we reach potential workforce from a young age and throughout the lifelong learning required for our evolving industry.

Awareness and Community Outreach	Next 1-2 years	Next 3-5 years
Establish K-12 instructional material and provide mechanisms for students and teachers to experience biofabrication activities		
Engage younger students in exploring biofabrication careers		
Align current educational frameworks (NGSS, Core, CTE) with biofabrication		
Engage undergraduate and graduate audiences in exploring biofabrication careers		
Establish connections with veterans associations		
Connect military and academic training facilities with local industry to establish local partnerships for collaboration		
Integrate biofabrication activities into expos, STEM camps, clubs, museums, etc.		

To begin work in this area, the 2018 Spring Project call aimed to:

- Engage and excite students in K-12
- Develop instructional material for integration into K-12 classrooms
- Provide mechanisms for students and teachers to experience biofabrication activities in order to increase the pipeline

The EWD Awareness and Community Outreach working group, established in 2019, gathers information across the ARMI | BioFabUSA ecosystem to begin connecting assets and opportunities throughout the network.

Future Workforce	Next 1-2 years	Next 3-5 years
Collect information on biofabrication education, training and careers		
Align biofabrication job positions with relevant skills to educational and training assets within BioFabUSA (competency pyramid) with annual refinement		
Support online and hybrid course that allow for regional flexibility		
Provide opportunities for educational and industry members to collaborate in developing and enhancing curriculum for biofabrication needs		
Examine how stackable credentials, certificates, and badges function at the various job levels in the industry		
Establish curriculum needs for regulatory, standards, and legal training		
Develop innovative mechanisms to provide hands-on learning for those in remote areas or not able to travel to training (e.g., virtual reality)		
Explore various methods of hands-on learning, including apprenticeships		
Ensure education and training pathways for veterans		

The initial data gathering provides a general view of biofabrication skill needs. The EWD Workforce working group assesses information from across the ARMI | BioFabUSA ecosystem so that industry-specific job skills can be matched with the educational and training opportunities available. Continued focus will allow for the identification of existing assets and strengths, and will identify gaps to address. As the technology for large-scale TEMP manufacturing evolves, so too will the training needs.

Abbreviations and Glossary of Terms

Abbreviations

ARMI: Advanced Regenerative Manufacturing Institute
CNC: Controlled Non Classified
CTE: Career and Technology Education
DoD: Department of Defense
EWD: Education and Workforce Development
GMP: Good Manufacturing Process
IT: Information Technology
NGSS: Next Generation Science Standards
QA: Quality Assurance
QbD: Quality by Design
QC: Quality Control
R&D: Research and Development
STEM: Science Technology Engineering and Math
TEMPs: Tissue Engineered Medical Products

Glossary of Terms

Biomaterial: non-viable material, either synthetic or non-synthetic (derived from human or animal sources), that has been engineered or purified to a consistent standard appropriate for use in medical or diagnostic applications.[5] A biomaterial can be used as a scaffold for seeding of cells prior to implantation or as a scaffold *in vivo* to promote native tissue repair; it can also include bioinks and other substrates used for additive manufacturing.

Quality by Design: A systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management.[6]

Tissue Engineered Medical Product (TEMP): a medical product that repairs, modifies or regenerates the recipient's cells, tissues, and organs or their structure and function, or both.[7]

[5] J. Kohn, J. Conroy, A. Danilkovitch, M. Francis, R. Guldberg, K. Healy, S. Kennedy, A. Khademhosseini, J. Krom, K. Leong, T. McDevitt, L. Niklason, M. Phaneuf and J. Steele, Biomaterials Solutions for Cell and Tissue Manufacturing: A "QuickStart" Roadmap for 2017, Prepared for the Advanced Regenerative Medicine Institute (ARMI), 2017.
[6] International Council for Harmonization. "Pharmaceutical Development: Q8(R2)," 2009.
[7] ASTM International Designation F2312-11. "Standard Terminology Relating to Tissue Engineered Medical Products"