Homeland Defense & Security Information Analysis Center

HDIAC TECHNICAL INQUIRY (TI) RESPONSE REPORT

Companies Who Develop and Manufacture Automated or Modular Biomanufacturing Systems

Report Number:

HDIAC-BCO-2025-657

Completed April 2025

HDIAC is a U.S. Department of Defense Information Analysis Center

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HDIAC is sponsored by the Defense Technical Information Center, with policy oversight provided by the Office of the Under Secretary of Defense for Research and Engineering. HDIAC is operated by the SURVICE Engineering Company.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE *(DD-MM-YYYY)*
30-04-2025

2. REPORT TYPE
Technical Inquiry Response Report (TIRR)

3. DATES COVERED *(From – To)*

4. TITLE AND SUBTITLE

Companies Who Develop and Manufacture Automated or Modular Biomanufacturing Systems

5a. CONTRACT NUMBER
FA8075-21-D-0001

5b. GRANT NUMBER

5c. PROGRAM ELEMENT NUMBER

5d. PROJECT NUMBER

6. AUTHOR(S)

Dennis F. Metz

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

Homeland Defense & Security Information Analysis Center (HDIAC)
SURVICE Engineering Company
4695 Millennium Drive
Belcamp, MD 21017-1505

8. PERFORMING ORGANIZATION REPORT NUMBER

HDIAC-BCO-2025-657

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)

Defense Technical Information Center (DTIC)
8725 John J. Kingman Road
Fort Belvoir, VA 22060-6218

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT

Distribution Statement A. Approved for public release: distribution is unlimited.

13. SUPPLEMENTARY NOTES
Biomanufacturing Systems, Automated Biomanufacturing Systems, Modular Biomanufacturing Capabilities

14. ABSTRACT
The Homeland Defense and Security Information Analysis Center (HDIAC) was asked to provide information on two separate but interrelated aspects of biomanufacturing capabilities: (1) what companies (global and American, if there are any) are developing/manufacturing automated biomanufacturing systems and (2) what companies are constructing/manufacturing modular biomanufacturing capabilities.

A highly detailed investigative research effort was conducted and focused on gathering relevant information to address the two separate but interrelated aspects of biomanufacturing capabilities. For purposes of this literature search, only companies who are constructing/manufacturing modular bioreactors comprise the modular biomanufacturing capabilities component of the effort.

From a literature search, this report has been generated and identifies the major companies and their associated systems that are automated biomanufacturing systems and modular biomanufacturing capabilities. This report includes results emanating from the broad search of companies categorized/classified as biomanufacturing companies. In addition, it presents results from the more highly focused search of companies deemed to be developing/manufacturing automated biomanufacturing systems.

15. SUBJECT TERMS (PROVIDED BY AUTHOR)
biomanufacturing, bioreactors, automated systems, modular systems

16. SECURITY CLASSIFICATION OF: U			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
					Ted Welsh, Operations Manager
a. REPORT U	**b. ABSTRACT** U	**c. THIS PAGE** U	UU	24	**19b. TELEPHONE NUMBER** *(include area code)* 443-360-4600

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

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TI Research

A chief service of the U.S. Department of Defense's Information Analysis Centers is free technical inquiry (TI) research limited to four research hours per inquiry. This TI response report summarizes the research findings of one such inquiry. Given the limited duration of the research effort, this report is not intended to be a deep, comprehensive analysis but rather a curated compilation of relevant information to give the reader/inquirer a "head start" or direction for continued research.

Abstract

The Homeland Defense and Security Information Analysis Center (HDIAC) was asked to provide information on two separate but interrelated aspects of biomanufacturing capabilities: (1) what companies (global and American, if there are any) are developing/manufacturing automated biomanufacturing systems and (2) what companies are constructing/manufacturing modular biomanufacturing capabilities.

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From a literature search, this report has been generated and identifies the major companies and their associated systems that are automated biomanufacturing systems and modular biomanufacturing capabilities. This report includes results emanating from the broad search of companies categorized/classified as biomanufacturing companies. In addition, it presents results from the more highly focused search of companies deemed to be developing/manufacturing automated biomanufacturing systems.

Contents

1.0 TI Request

1.1 Inquiry

What companies (global and American, if there are any) are developing/manufacturing automated biomanufacturing systems, and (2) what companies are constructing/manufacturing modular biomanufacturing capabilities?

1.2 Description

The Homeland Defense and Security Information Analysis Center (HDIAC) was asked to conduct an investigative research effort focused on gathering relevant information to address the two separate but interrelated aspects of biomanufacturing capabilities: (1) automated biomanufacturing systems and (2) modular biomanufacturing capabilities.

1.3 Notes on Key Definitions

There are five key terms and their associated definitions that are pivotal to ensuring an understanding of the information gathered from this investigative research effort:

1. Biomanufacturing
2. Automated Biomanufacturing System
3. Modular Biomanufacturing Capability
4. Modular Bioreactor
5. Bioreactor

Definitions associated with each term are presented in Sections 1.3.1–1.3.5.

1.3.1 Biomanufacturing

According to the EuropaBio website [1]:

> Biomanufacturing is the use of biological mechanisms to i) synthesize products, ii) act as tools, or iii) undertake processes, at a scale required for commercial use. Biomanufacturing can use different sources for the desired biological mechanisms:
>
> - Animal and human cells
> - Plants, either individual cells or whole plants

- Microorganisms such as yeast, bacteria, fungi, and microalgae
- Viruses

Biomanufacturing can either use biological processes to synthesize desired products, or the biological material is the product itself.

1.3.2 Automated Biomanufacturing System

An automated biomanufacturing system is [2]:

> …a system that integrates various technologies and equipment to automate the production of biological products, such as biopharmaceuticals, vaccines, enzymes, biofuels, and other biomolecules. This automation aims to streamline and optimize the biomanufacturing process, reducing the need for manual intervention and improving efficiency, consistency, and product quality.

1.3.3 Modular Biomanufacturing Capability

Modular biomanufacturing capability is an "assembly of preconfigured, [standardized, integrated] processing elements, each with a finite, but not necessarily inflexible, functionality. These modular elements can be as small as single unit operations or…can be combined to form more complex processing solutions" [3].

1.3.4 Modular Bioreactor

A modular bioreactor is a [4]:

> …versatile system that offers a range of characteristics tailored to the needs of bioprocessing (or biomanufacturing) applications. [The modular bioreactor is] designed with modularity in mind, allowing for flexibility in terms of configuration and scalability. Key characteristics include the ability to easily add or remove modules to accommodate different process requirements, such as varying vessel sizes, agitation systems, and sensor configurations.
>
> A modular bioreactor often features advanced control systems that enable precise regulation of crucial parameters, including temperature, pH, dissolved oxygen, and agitation speed. [In addition], the modular

bioreactor may integrate online monitoring and control capabilities for real-time data acquisition, process optimization, and automated feedback control.

1.3.5 Bioreactor

Based on a review by G. Regonesi [5]:

> A bioreactor, or a fermentation vessel, is a device or system used to cultivate and produce biological cells, tissues, or organisms in a controlled environment. It functions as a vessel-like equipment that offers a stable environment for microorganisms to thrive while also maintaining a steady equilibrium in the biochemical processes carried out by these bacteria to produce the necessary chemicals.

2.0 TI Response

The inquirer asked HDIAC to provide information on two separate but interrelated technical inquiries (TIs):

1. What companies (global and American, if there are any) are developing/manufacturing automated biomanufacturing systems?
2. What companies are constructing/manufacturing modular biomanufacturing capabilities?

A comprehensive literature search was conducted and entailed leveraging two critical sources of information:

1. Unclassified/unlimited information resident in the Defense Technical Information Center
2. Open-source information located in various internet search engines (e.g., Google, Yahoo, Bing, Swisscows, DuckDuckGo)

2.1 What Companies (Global and American, if There Are Any) Are Developing/Manufacturing Automated Biomanufacturing Systems?

In response to this TI, the detailed literature search proceeded from a broad search of companies categorized/classified as biomanufacturing companies to the more highly focused search of companies deemed to be developing/manufacturing automated biomanufacturing systems.

Companies involved in developing/manufacturing automated biomanufacturing systems and their associated automated biomanufacturing system(s) are detailed in Sections 2.1.1–2.1.10.

2.1.1 Ananta Technologies, Inc.

Anata Technologies, Inc.'s (Pillman, WA) CentriFLEX is designed [6]:

> …to optimize the manufacturing process. [It is] a centrifugal fluidized expansion (CentriFLEX) perfusion bioreactor that balances centrifugal forces with a continuous feed of fresh media. Unlike current expansion systems, the CentriFLEX resolves a key manufacturing bottleneck in continuous cell culture—prevention of cell product loss while simultaneously feeding fresh media and removing inhibitory waste. The CentriFLEX also eliminates the need for membrane filters used in current perfusion bioreactors, which are prone to fouling, an expensive and prominent issue.

2.1.2 Alphinity LLC

Alphinity LLC's (Carson City, NV) Polymorphic Process System is a fully automated bioprocessing system that brings adaptability and efficiency to both upstream and downstream single-use processing [7].

2.1.3 Conagen, Inc.

Conagen, Inc.'s (New Bedfored, MA) Conamax is a "robust, rapid, and inexpensive microbial antibody production platform for antibody developers and the global patient populations they serve" [8].

2.1.4 Culture Biosciences

Culture Biosciences (South San Francisco, CA) offers the Culture 250ml bioreactor and the Culture 5L pilot-scale bioreactor. The Culture 250ml bioreactor can be used for mammalian, microbial, viral vector, and media development. This bioreactor has a wide range of applications across process development, process optimization, and process characterization [9].

The 5L pilot-scale bioreactor is "designed for key stages of bioprocess development, including mammalian cell culture scale-up, microbial fermentation, and viral-vector process development." The 5L bioreactor is quite versatile by being able to support "media development and enable efficient transitions to large-batch production and preclinical bioprocessing" [10].

2.1.5 Cytiva

Cytiva (located in Marlborough, MA, and part of the Danaher Corporation) offers the Xcellerex Automated Perfusion System (APS). It "is a single-use system for both process development and production." The tangential flow filtration-based system can be used "for intensified [current good manufacturing practice] cGMP manufacture of preclinical material." The APS performs a variety of "upstream applications including classic steady state and N-1 perfusion" (i.e., N-1 perfusion is intensification of cell growth in the seed train step [N-1] before the production bioreactor [N]). In addition, the Xcellerex APS performs techniques using ultrafilters by integrating the multifunctional system with Xcellerex XDR family (50, 200, 500, 1,000 and 2,000 liter) "to enable perfusion capability." Note that the Xcellerex XDR family of single-use bioreactor systems provides scalable and robust stirred-tank performance for up to 2,000 liters in both cGMP and non-cGMP environments [11].

2.1.6 FUJIFILM Diosynth Biotechnologies Inc.

FUJIFILM Diosynth Biotechnologies Inc. (Morrisville, NC) has the MaruX, which is "a fully automated continuous manufacturing platform. [It] features single-use perfusion bioreactors for unsurpassed high-density cultures, while all downstream process steps are connected and handled by SymphonX, a fully automated and highly customizable purification platform." Note that it is not clear from the literature search whether MaruX can be purchased from the company [12].

2.1.7 Honeywell International Inc.

Honeywell International Inc. (Charlotte, NC) introduced the TrackWise Life Sciences Platform in early 2025. It is "a purpose-built solution designed to revolutionize the way life sciences organizations approach integrated manufacturing and quality management, through digital transformation and advanced automation. TrackWise addresses critical needs across quality, manufacturing, and postmarket activities through an integrated open ecosystem" [13].

2.1.8 Rockwell Automation

Rockwell Automation (Milwaukee, WI) offers FactoryTalk PharmaSuite [14]:

> It is the leading [manufacturing execution system] MES solution developed specifically for the life sciences industry. It provides role-based optimization for each life-cycle stage and [produces faster] time to results for all users. Its open-content architecture, paired with an intelligent upgrade engine, provides a robust system for growth in both batch and discrete processing.

2.1.9 Sartorius AG

Sartorius AG (Göttingen, Germany) offers the Ambr 15 Cell Culture Generation 2 system, which is “an automated, high-throughput, microscale bioreactor system.” It reproduces “laboratory-scale bioreactor performance.” The system comprises “single-use vessels, an automated workstation, and powerful software” [15].

Biobrain is a standard Sartorius automation platform powering Sartorius process units for upstream and downstream processing, as well as fluid management technologies. It is specifically tailored to be applied in regulated pharmaceutical and biopharmaceutical production environments [16].

2.1.10 Siemens AG

Siemens (Munich, Germany) offers smart biomanufacturing solutions that leverage personalization, modularization, and digitalization. These solutions enhance efficiency and speed in small-scale production lines with single-use components while maintaining quality. Siemens provides flexible automation systems, powerful process analytical technology tools for process data integration, and electronic batch recording systems. These technologies enable thorough process understanding, increased production flexibility, and “right-first-time quality” in biopharmaceutical production [17].

2.2 What Companies Are Constructing/Manufacturing Modular Biomanufacturing Capabilities?

In response to this TI, two specific elements had to be considered. The first embodies the broader and diverse component referred to as “modular biomanufacturing capabilities.” The second encompasses the key constituent characterized as “modular bioreactors,” which is essentially a subset of the overarching “modular biomanufacturing capabilities.” A critical step in determining the most relevant information selected from the literature search was to define the terms “modular biomanufacturing capability” and “modular bioreactor.” These two terms have been previously defined in Sections 1.3.3 and 1.3.4. These definitions not only serve as a reference point but also provide a frame of reference for what information has been selected from the literature search.

It is important to recognize that, regardless of whether one considers either a modular biomanufacturing capability or a modular bioreactor, the two share a common framework regarding the modular design aspect. That is to say [18]:

> A modular design approach considers each process unit operation as an independent module, including process equipment, utilities, and personnel, and then defines what the process envelope should be from a dimensional and environmental perspective. These modules are then combined to form a complete manufacturing process.

For purposes of this literature search, only companies who are constructing/manufacturing modular bioreactors have been selected. Companies involved in developing/manufacturing modular biomanufacturing systems and their associated modular biomanufacturing system(s) are discussed in Sections 2.2.1–2.2.9.

2.2.1 bbi-biotech GmbH

bbi-biotech GmbH (Berlin, Germany) offers the xCUBIO bioreactors, which “cater to a wide spectrum of bioprocess applications, from intricate research and development projects to large-scale production efforts.” One distinct feature/advantage of the xCUBIO single, twin, and multiconfigurations is sensor interface customization that can be provided by bbi-biotech with a “diverse selection of sensor interfaces, ensuring precise monitoring and control across all phases of [the] bioprocess” [19].

2.2.2 Cytiva

Cytiva (located in Marlborough, MA, and part of the Danaher Corporation) offers the Xcellerex X-platform bioreactors, which are touted as next-generation single-use bioreactors for higher performance, reliability, and flexibility. These next-generation bioreactors are available in two different sizes: (1) 200 liters and (2) 50 liters. These bioreactors run on Figurate automation powered by Rockwell Automation’s PlantPAx distributed control system. It is important to note that no information was found on the company website to indicate that these next-generation single-use bioreactors can be configured as parallel bioreactors (i.e., set up as multiple bioreactors in parallel to perform bioprocessing) [20].

2.2.3 Distek, Inc.

Distek, Inc. (North Brunswick, NJ) offers the BIOne 1250 Dual Bioprocess Control Station. This station allows end users simultaneous control of two independent bioreactor or fermentation systems from a single central tower [21].

In addition, the company offers the BIOne single-use bioreactor, which can be interfaced with the BIOne 1250 Dual Bioprocess Control Station. The BIOne single-use bioreactor is compatible with a range of bioprocess controllers, which makes it an ideal choice for researchers, scientists, and bioprocess engineers seeking a reliable and efficient system for their experiments or production processes [22].

2.2.4 Eppendorf SE

Eppendorf SE (Hamburg, Germany) offers the BioBLU c single-use bioreactors, which “are rigid-walled stirred-tank bioreactors for the cultivation of human and animal cells. The scalable BioBLU c portfolio allows for a 400-fold cell expansion (working volume range of 100 mL–40 liters)” [23].

In addition, Eppendorf SE offers the BioBLU f single-use bioreactors, which are also “rigid-walled stirred-tank bioreactors specifically designed for robust microbial applications using bacteria, yeasts, and fungi. The scalable BioBLU f portfolio covers a working volume range of 65 mL–3.75 liters” [24].

Another product offered by Eppendorf SE is the SciVario twin [25]:

> The SciVario twin is a bench-scale parallel bioprocess controller capable of operating two bioreactors individually. It is suitable for cell culture and fermentation applications in [research and development] R&D and can be used with glass and BioBLU single-use bioreactors. The SciVario twin is a modular system, making it customizable, as well as easily upgradable after installation and, therefore, adaptable to changing requirements.

The company also offers the DASbox mini bioreactor system, which [26]:

> …is a parallel bioreactor system for research and process development in small working volumes. It can operate up to 24 glass or BioBLU single-use bioreactors in parallel and is suitable for microbial fermentation and cell culture, including the cultivation of stem cells, with working volumes from 60 mL to 250 mL.
>
> The DASware software suite enables precise monitoring and control of critical process parameters, as well as the implementation of tailored feedback loops, feeding strategies, and other features.

The company also offers the DASGIP Parallel Bioreactor System, which [27]:

> …is a bioreactor system for research and process development in working volumes from 200 mL to 1.8 liters. It can operate up to 16 glass or BioBLU single-use bioreactors in parallel and is suitable for microbial fermentation and cell culture, including the cultivation of stem cells. The modular design allows users to choose the most suitable configuration for their application needs.

It also offers the DASware software suite previously described with the DASbox.

2.2.5 GBC Bio

GBC Bio (Perigny, France) offers stainless steel bioreactors in an assortment of sizes. Their modular design and variety of options available allows them to be personalized. The C-BIO$_2$ operator and control platform provides enhanced functionality and process control options, as well as full integration and connectivity to GPC Bio's Process Line equipment and third-party (equipment) supervisory software, making it the ideal platform for automation and data integration of the process [28]. The C-BIO$_2$ is the control software for all GPC Bio installations. It can accommodate up to six bioreactors [29].

2.2.6 Knik Technology

Knik Technology (Shanghai, China) offers several different parallel glass bioreactors (e.g., 2 conjoined glass bioreactors, 4 conjoined bioreactors, quadruple glass bioreactors, 8–10 conjoined bioreactors). Siemens programmable logic controller (PLC) serves as the control system [30].

2.2.7 SATAKE MultiMix Corporation

SATAKE MultiMix Corporation (Saitama, Japan) offers a variety of single-use bioreactors in a scalable lineup, from small scales for laboratories, to pilot scales, to large scales for production. These single-use bioreactors encompass vertical reciprocating bioreactors, rotational bioreactors, and rotary bioreactors with a high-gas-dispersion turbine. It is important to note that no information was found on the company website to indicate that these single-use bioreactors can be configured as parallel bioreactors (i.e., set up as multiple bioreactors in parallel to perform bioprocessing) [31].

2.2.8 Sartorius AG

Sartorius AG (Göttingen, Germany) offers the ambr 250 modular single-use benchtop bioreactor [32]:

> [It] is an innovative, new high-performance benchtop bioreactor system for parallel microbial or cell culture in 100–250-mL single-use vessels. The system utilizes the same advanced stirred tank bioreactor technology pioneered in the original ambr 250 high-throughput system. The system comprises a series of benchtop modules enabling 1–8 bioreactors to be operated in parallel and a control module with intuitive system software accessed via a user-interface screen.

The ambr 250 modular single-use benchtop bioreactor is designed to achieve high productivity, scalability, ease of use, and expandability [32].

2.2.9 Solida Biotech GmbH

Solida Biotech GmbH (Munich, Germany) offers advanced modular bioreactors [33]:

> [The] advanced modular bioreactor series represents the latest advancements in automation, software, and mechanical engineering applied to the bioprocess industry.
>
> [The modular bioreactors provide] high-flexibility, modularity, easy upgrades and replacements, guaranteed long-term spare part availability, and after-sales service.

> The modularity and flexibility of [the] control unit offer the unique advantage of being able to start with 1 bioreactor that can then be upgraded to 2-4-6-12-24 and up to 36 bioreactors working online with the same or different vessel size and typology.
>
> [The] BioController module incorporates industry-leading PLC hardware, ModBus, and Ethernet communication protocols to simplify and accelerate single and parallel bioreactor operations.

3.0 Conclusions

Section 3.1 provides conclusions drawn from literature search results that address what companies (global and American, if there are any) are developing/manufacturing automated biomanufacturing systems. Section 3.2 provides conclusions drawn from literature search results that address what companies are constructing/manufacturing modular biomanufacturing capabilities.

3.1 Conclusions Addressing Companies That Are Developing/Manufacturing Automated Biomanufacturing Systems

These conclusions are drawn from two perspectives: (1) a broad search of companies categorized/classified as biomanufacturing companies and (2) a highly focused search of companies deemed to be developing/manufacturing automated biomanufacturing systems.

The conclusions drawn from the broad search are:

- There are a countless number of large and small companies that can be categorized/classified as biomanufacturing companies.
- These biomanufacturing companies are located not only in the United States but also throughout the world.
- These biomanufacturing companies are predominantly in the business of developing/producing products that are not designed for the purposes of selling automated biomanufacturing systems. Instead, the focus is on developing/producing products in the areas of life-science research (e.g., live cell assays, sample preparation, infectious diseases), biopharmaceutical manufacturing (e.g., monoclonal antibodies, vaccines, cell line development), cell and gene therapy, and quality control processes and measures.

The conclusions drawn from the highly focused search are:

- The companies who are developing/manufacturing automated biomanufacturing systems are the companies that tend to be more visionary and forward thinking. These companies are one step ahead of the competition in biomanufacturing technology.
- Several of the leading companies associated with automated biomanufacturing systems have indicated the following:
  - Automation will play a greater role in biopharmaceutical operations, particularly in moving material between sites in the production process. Integral to this automation process will be the utilization of robotic systems, which will play a bigger role regarding material movement.
  - Digital transformation is a growing global industry capability that leverages networking and smart technologies to integrate all processes, from sourcing and manufacturing to distribution.

3.2 Conclusions Addressing Companies That Are Constructing/Manufacturing Modular Biomanufacturing Capabilities

These conclusions are also drawn from two perspectives: (1) the broader and diverse component referred to as modular biomanufacturing capabilities and (2) the key constituent characterized as modular bioreactors.

The conclusions drawn from the modular biomanufacturing capabilities component are:

- Both large and small biomanufacturing companies are moving toward the design concept of modular biomanufacturing. This includes U.S.-based biomanufacturing companies as well as nondomestic biomanufacturing companies.
- The modular biomanufacturing concept is recognized as a means to scale production capacity more easily and, ultimately, decrease overall production cost and reduce the time to market for the product.
- The modular biomanufacturing design has been demonstrated to yield benefits throughout the complete life cycle of a biomanufacturing facility.

The conclusions drawn from the modular bioreactor capabilities component are:

- A substantial number of companies, both large and small, are involved in constructing/manufacturing modular bioreactors. This includes both U.S.-based companies as well as nondomestic companies.
- Modular bioreactors provide numerous benefits over nonmodular bioreactors. These include greater flexibility in scalability, the capability to operate multiple bioreactors in parallel, and a small footprint that results in greater lab space efficiency and increased cost effectiveness.

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Biography

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