



CALL FOR PROPOSALS

Apply before June 15

Looking for an industrial verification environment for your innovative bioprocess technology? Apply to Testa Challenge!

Biological drugs and products are transforming medicine and promise future targeted treatments for a range of conditions. However, in order for these powerful products to benefit all people in the world, a large number of new technologies and tools that can drastically improve productivity of biological production are needed. New methods, processes and approaches are required to accelerate innovation in this area.

We have identified three main challenges within the field of bioprocessing;

Sustainability



The advanced manufacturing process of biological drugs need sustainable and cost-effective solutions to reduce waste, increase energy efficiency and drive sustainability which requires innovations in several fields.

Productivity



The increasing demand of new and innovative biological drugs puts pressure on the bioprocess industry to deliver tools that enable greater productivity to maximize yield and speed of production. What are your possibilities to tackle the demand?

Control



Imagine seamlessly executing workflows while having instant access to the data needed to better understand the processes and make informed decisions. What are we missing to better understand our processes?

We know that there are countless promising technologies out there. We also know that, as a young technology developing company, it can be a significant threshold to get access to a relevant industrial verification environment.

In order to address this gap, Testa Center now invite you to apply to the **Testa Challenge**.

Projects and companies from the **Technology/Digital/Data** segment are invited to integrate, test and verify their innovation, in a fully funded standard bioproduction workflow at Testa Center. Alongside the production process, participants will be supported by experts.

The provided facilities, expertise and fast-tracked application will allow an early evaluation whether the innovation is applicable and successful for the bioprocessing industry. The production process will be designed to include ~5 selected technologies and run in Testa Center during October 2020*.

**pending detailed planning and careful monitoring of any restrictions issued by the authorities due to the Corona pandemic*



Who can apply?

The call is open for projects and companies from all entities (academic, start-ups, larger companies and institutes) from all countries. Testa Center is situated in Uppsala, Sweden, and the experiments will be performed in our premises. For applicants outside Europe, please contact us before applying so that we can discuss your capability to participate on site.

We welcome all kind of innovative solutions that have the potential to meet the future technology needs and challenges within bioproduction. Some examples in the area of technology include sensors, separation technology, pumps, etc. Within the digital/data segment, some examples include cloud solutions, VR / AR, AI, data transfer, modeling, smart automation, smart laboratory tools, new tools to monitor the quality processes etc.

The proposed project can be a solution for any stage in the bioprocess workflow, from preparation and planning to the actual culture, harvest and downstream activities such as separation and purification.

After the challenge you will have reduced product development risks for your innovation by having verified the concept. This in turn will enable other investments on your journey towards market introduction. The goal is that the activities brought to you by the Testa Challenge shall make an evident difference in the development stage and the value of the project.

Accepted Technical Readiness Levels (TRL) will be 3-9. For early projects, typically TRL 3-4. Data from lab/bench-tests is to be included in the application, in order to assess whether a full-scale bioproduction workflow is applicable at this stage. We welcome up to TRL 9, which means product on the market. For details on TRL levels, please refer to Appendix 1.

In general, routine or recurring changes or updates of existing products, methods, services or processes are not in focus of this challenge, although such changes may represent improvements.

The Testa Challenge bioprocess workflow – specifications

The run will be a start to finish bioprocess where a protein, a domain antibody fragment, dAb, will be produced and purified.

- Brief process outline:
- Production of dAb in *E.coli* in a 50 L bioreactor
- Release of dAb to periplasm through heat treatment
- Cell separation and filtration
- Purification of dAb using affinity chromatography

For more details on timelines and technical specifications please refer to “**Technical description Testa Challenge**” which will be available at www.testachallenge.com.

What type of solutions and projects can be proposed?

Focus for the Testa Challenge is fully funded standard bioproduction workflow as described above. The run will be performed at the Testa Center Uppsala Sweden during one week in October* (to be planned). Suggested projects need to fit in the scope of the described process or relatively easily be integrated into the workflow. It is expected that selected projects actively participate in person at Testa Center during the run.



Examples of possible solutions and project scopes within the challenge “Sustainability”:

- Waste reduction – renewable sources, shift to a useful resource, less byproducts
 - New innovative materials providing greener solutions
 - New solutions for sterile connect/disconnect for process sampling
- Increase in energy efficiency
 - Low-energy sensors, smaller sensors
- Artificial Intelligence/Machine learning capabilities
 - Digital twin to reduce failure rate

Examples of possible solutions and project scopes within the challenge “Productivity”:

- Yield performance
 - Computer modeling as a measure to maximize yield
- New methods for separation of biomolecules
 - New innovative materials providing better coating, flowrates, etc.
- Speed of production
 - New sensor for on-line measurements of end-point levels
- Automation of workflow
 - Robotics to aid biomanufacturing processes

Examples of possible solutions and project scopes within the challenge “Control”:

- Data management systems to address unmet analytical data needs, such as:
 - System communication
- Decision support tool for risk reduction
 - Process monitoring tools
- New technologies for wireless data transfer
 - Best practices
- AI/Machine learning capabilities
 - Reduce bias or human error
- New tools to monitor the quality processes
 - Increased quality control information

Not included in this call:

- Biological up-scaling processes
- New biological tools and innovations such as new production vectors, new biologic approaches for maximizing yield, biological growth matrices, and Expression systems.
- Chemistry-related projects such as new additives, media, substrates, etc.

Testa Challenge offers you

A bioprocess workflow

The Testa Challenge gives open access to an authentic industrial bioprocess environment, where you can verify your technology in an industrial setting.

Experiment design support and access to expertise

Selected projects will receive support with detailed experimental planning, continued support and access to expertise in the preparation phase, all maximizing likelihood of success.

Continued ownership

The projects retain full ownership of their technologies.



Faster development by support and access to network of experts

Supported by the Testa Center specialists, as well as getting access to a large network, your chances for successful project execution increases. After project completion, the goal is that your project has reduced risks by having verified the concept enabling other investments on your journey towards market introduction.

Get visibility of your innovative technology

Testa Challenge will be a great window for your technology. Throughout the Testa Challenge, we will show-case the participating projects to the bioprocess community. The Testa Center will therefore be a great opportunity to expose you for potential future collaboration partners and customers.

How are projects selected?

Representatives from industry together with investors constitute the selection board that will select the most promising proposals. The projects are selected based on the following criteria:

- Need and demand of the proposed solution
- Potential to meet the future technology demands within bioproduction
- Commercial potential and scalability
- Innovative height
- How well the proposed project fits into the scope of the Testa Challenge
- Project Benefits to participate in Testa Challenge

As a part of the selection process, all applications will be subject to a feasibility check performed by specialists at Testa Center, to make sure that the suggested project can be integrated into the planned bioprocess workflow. For this reason, we encourage you to contact us prior to applying to discuss your proposal.

Terms

Applicants will retain all rights to their technologies, data and know-how.

Applications will be handled discretely, and only selected projects will be made public. Nevertheless, we do not recommend you to include any confidential information in the application. After selection, all admitted applications will be deleted from our servers, and reviewers will be prompted to the best to delete files.

For practical reasons, it will not be possible to keep data from the actual bioreactor and protein purification run confidential. As a consequence of this, we do not recommend projects with non-protected technologies (i.e. no patent application submitted or no strategy for how to keep trade secrets) to participate in the Testa Challenge. If you have any questions regarding this, please contact us to discuss further.

The focus of the Testa Challenge is verification, not innovation. Still, new ideas might arise when we bring together bright minds during the Testa Challenge week. In order to be able to handle rights to potential new IP, selected projects will be prompted to summarize their background IP before start of the Testa Challenge week.

Selected projects are expected to actively participate in the planning phase, starting July/August 2020. An experienced Testa Center specialist will work together with your team in order to prepare a detailed plan for the Testa Challenge week.

Access to the Testa Center facilities and participation in Testa Challenge is conditional upon signing an Access Agreement, including the applicable terms and conditions for use of and access to the premises and equipment. The entire Access Agreement is available upon request. Specifically, the applicant is invited to study the terms and conditions applicable for result ownership and confidentiality, as set out in Appendix 2.



For selected projects, it is mandatory to participate on site in Uppsala and perform the verification work during the Testa Challenge Week. Due to the Corona pandemic and potential travel restrictions, we will work closely together with selected teams and monitor the situation, and if needed, we will make our best efforts to try to find alternative solutions.

The applicant is responsible for the work environment for its Individual Users while working on Testa Center premises during Testa Challenge Week, as set out in the Work Environment Act (Swedish law "Arbetsmiljölagen" SFS 1977:1160). Testa Center has a coordinating role for the Premises.

The event will be free of charge, however there will be a no-show fee of 20 000 SEK. (Not applicable if travel restrictions due to Corona pandemic are still effective).

Selected projects are encouraged to communicate externally prior, during and after the Testa Challenge, and we will be happy to support you with this. We will also communicate externally and show-case selected projects.

The Testa Challenge is hosted and administered by Testa Center in Uppsala, Sweden, in collaboration with STUNS Life Sciences and Cytiva. The Challenge is supported by Region Uppsala.

Welcome with your application

It's easy to apply to Testa Challenge online at www.testachallenge.com.

We're here to help you with your application. We are happy to provide you with feedback on your proposal, and in order to receive feedback, your proposed application must be submitted by June 5.

You are also welcome to contact us at testachallenge@testacenter.com to book an individual coaching session on May 28 for feedback on your proposed application.

The deadline for project proposals is **June 15th, 2020 at 22.00 CET**.

Questions? Do not hesitate to contact us!

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Testa Challenge is made possible thanks to:



About Testa Center

Testa Center is a non-profit company owned by Cytiva (formerly GE Healthcare Life Sciences). Testa Center is a major initiative between the Swedish government and Cytiva to secure the growth of life science industry and its manufacturing capabilities. Main objective for Testa Center is to bridge the gap from discovery to industrialization.

We offer businesses and academia globally a modern, pilot-scale testbed for projects and education in production of biological products e.g. monoclonal antibodies, peptides, protein, vaccine and viral vectors (non-GMP, up to Bio-safety level 2 and 500 liter).

In our flexible facility, and with some helping hands of our experienced staff, you can perform a wide variety of projects, including scale-up of parts of a process, or a complete process from frozen cell bank vial to purified protein.

www.testacenter.com

About Cytiva (formerly GE Healthcare Life Sciences)

We are a global provider of technologies and services that advance and accelerate the development and manufacture of therapeutics. We are nearly 7000 associates with operations in 40 countries. We are a trusted partner to customers who do things ranging from fundamental biological research to making life-saving vaccines, biologic drugs and novel cell and gene therapies. Some of our customers use our products in industries outside of biological research.

Our vision is a world in which access to life-changing therapies transforms human health. Our everyday work leads us step by step toward this vision.

Our mission is advancing and accelerating therapeutics. We supply the tools and services – the pots, pans, soups and sauces - that help our customers do their work better, faster, and safer. Some of our products, such as filters, can also support a range of applications in industries outside of biological research. Everything we do is essential to the entire process – from start to finish and in between. We advance the work of our customers for better patient outcomes.

www.cytivalifesciences.com



Appendix 1 – TRL Technology readiness levels:

TRL	General description of TRL	Example: Technology based solutions	Example: Software based solutions
TRL1	Basic principles and research data observed and reported	Scientific research findings are reviewed and assessed, and translation into applied research and new technologies begun.	Scientific research begins to be translated into applied R&D activities. Concepts evaluated that can be implemented in development of e/m-technology (software, sensors, devices, infrastructure or process).
TRL2	Technology concept and/or practical application formulated	Hypothesis, research ideas, protocols and experimental designs are developed. The potential ability of particular technologies, materials, and processes to address certain health problems identified.	Invention of potentially practical technology solutions addressing particular needs.
TRL3	Analytical and experimental Proof of Concept of critical function and /or characteristics	Active R&D initiated. Hypothesis testing, data collection, identification and evaluation of critical technologies and components and early proof of concept in laboratory models.	Active R&D initiated. Analytical studies to validate predictions of technology components of the technology that satisfy a need – forming the system application. System application tested in laboratory environment
TRL4	Validation of the technology in the laboratory	R&D. Laboratory testing of critical components and processes. Proof of concept of device demonstrated in relevant laboratory models.	System components integrated and tested regarding preliminary efficiency and reliability. Software architecture and other system components development to address reliability, scalability, operability, security etc. Other system components development
TRL5	Validation of technology in a relevant environment	Further development of device candidates and system solutions. Validation of system components and processes in relevant laboratory environment. Classification of device by appropriate regulatory body.	System component architecture established. System tested in relevant testing environment as expected in the operational environment. Verification, validation and accreditation when appropriate initiated.
TRL6	Demonstration of technology in relevant environment	System/device prototype demonstrated in an operational environment.	Representative model or prototype system demonstrated in relevant live or simulated environment. System component releases are “beta” versions and configuration controlled. Support structure in development and verification and validation and when needed accreditation for safety reasons in progress.
TRL7	Technology prototype demonstrated in an operational environment	Validation conducted using a fully integrated prototype version of the device in an operational environment. Data evaluated to support further development The final product design validated and final prototype and/or device intended for commercial use produced and tested.	System tested in an operational environment. Support structure in place and System component releases in distinct versions. Verification, validation and when appropriate accreditation completed.
TRL8	Technology system completed and qualified through test and demonstration	Development completed. Relevant regulatory approvals achieved.	Development completed. System demonstrated to work under real life conditions. Testing of design specifications. System component releases are production versions. Support structure in place to resolve technical issues. Relevant regulatory approvals achieved.
TRL9	Technology system in its final form ready for full (commercial) deployment in relevant operating environment	Product launched.	Product launched.



Appendix 2 – Result ownership and confidentiality clauses:

Access to the Testa Center facilities is conditional upon signing an Access Agreement, including the applicable terms and conditions for use of and access to the premises and equipment. The entire Access Agreement is available upon request. Specifically, the applicant is invited to study the terms and conditions applicable for result ownership and confidentiality, as set out below.

Any result invented, generated or otherwise created on the Premises during the Project Term by Client, shall be solely vested in the Client. In the event Client invents, generates or otherwise creates Result within Other Client Field, Client shall grant such Other Client (a) a non-exclusive royalty-free perpetual license to use such result also for commercial purposes within Other Client Field, and (b) a right to negotiate on fair and reasonable terms an exclusive license to use such result.

The Client acknowledges that the Premises is an open innovative environment and that during the Project Term, Other Clients and their Individual Users will simultaneously have access to and use the Premises for individual projects. When performing their individual project on the Premises during the Project Term, Other Client may disclose and/or share information with Client which is confidential to Other Client, and which may or may not be proprietary to Other Client ("Confidential Information"). Client and its Individual Users may also otherwise have access to Other Client's Confidential Information at the Premises during the Project Term. Client acknowledges and undertakes that neither Client nor its Individual Users shall use, for its own or others' purposes, or disclose to anyone, information which is reasonably understood to be Other Client's Confidential Information and which Client has received or otherwise learned at the Premises during the Project Term.

Client acknowledges that the confidentiality undertaking above is made not only towards Testa Center but also and specifically towards any and all Other Client.