CALL FOR PROPOSALS

Apply before October 25th

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

Testa Center and STUNS Life science invite you to apply to the **Testa Challenge 2023** in collaboration with Cytiva.

Testa Challenge is where projects and companies from the **Technology/Digital/Data** sector 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 in the field.

The provided bioprocess, facilities and expertise will allow an early evaluation of whether your innovation is applicable and successful for the bioprocessing industry. The process will be designed to include multiple participating and selected technologies and run at Testa Center for three weeks starting **March 13th, 2023****.

** Companies must be eligible for de minimis aid*
*** Pending detailed planning and careful monitoring of any restrictions issued by the authorities due to the Corona pandemic*

Why verify in an industrial bioprocess environment?

Biological drugs and products are transforming medicine and promise future targeted treatments for a range of conditions. However, for these powerful products to benefit all people in the world, 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 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. Testa Challenge was created to address this gap.

If you are curious about the selected projects in the previous Testa Challenges, you can learn more here.

Who can apply?

The call is open for Small and Medium-sized Enterprises (SME) globally eligible for de minimis aid*. Testa Center is situated in Uppsala, Sweden, where the experiments will be performed. We expect the selected projects to actively participate in various planning activates prior to the Testa Challenge Weeks as well as on site during parts of the weeks**. For applicants outside of Sweden, please contact us before applying so that we can discuss your capability to participate on site.

** De minimis aid refers to support that is not covered by state aid rules. If you have not received support over the maximum amount of EUR 200 000 from Swedish actors over the past 3 years, you are eligible. (For more information about de minimis please click here).*
*** Note that this obligation may change due to the ongoing pandemic.*

The Testa Challenge bioproduction workflow – specifications

The Testa Challenge bioproduction will be a start to finish bioprocess where an adeno associated virus (AAV) will be produced and purified in an industrial environment. Below is a process outline:

- Production of AAV in a HEK cell expression system using a single use bioreactor
- Clarification of the culture using filtration
- Purification of AAV using affinity chromatography followed by an additional polishing step with multimodal chromatography
- Product analysis

For more details on timelines and technical specifications stay up to date on the website during September.

What type of solutions and projects can apply?

Proposed projects need to fit in the scope of the described bioprocess above or relatively easily be integrated into the workflow. It can be a solution for any stage in the bioprocess, from preparation and planning to the actual culture cultivation, harvest and downstream activities such as separation and purification.

The accepted Technical Readiness Levels (TRL) of your technology is from TRL 3 up to TRL 9 where the latter is product on the market. For details on TRLs, please refer to Appendix 1. Data from lab/bench-tests is to be included in the application, to assess whether a full-scale bioproduction workflow is applicable at the current stage of your technology.

We welcome all kind of innovative solutions that have the potential to meet the future technology needs and challenges within bioproduction where we have identified the three main challenges as:

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?

Some examples of innovative solutions to meet the above challenges in technology include sensors, separation technology, pumps, etc. Within the digital/data sector, some examples include cloud solutions, VR /AR, AI, data transfer, modeling, smart automation, smart laboratory tools, new tools to monitor the quality processes etc.

Below follows lists of examples of possible solutions and project scopes within the different field of challenges.

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
    - Process analytical technology (PAT)

<u>Not</u> 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.

What does Testa Challenge offer you?

Besides the weeks full of inspiring lectures and other activities Testa Challenge offers:

A bioproduction 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.

Visibility of your innovative technology

Throughout the Testa Challenge, we will show-case the participating projects to the bioprocess community. The Testa Challenge will therefore be a great opportunity to expose you to 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 the 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 bioproduction 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 including 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 Weeks. To handle rights to potential new IP, selected projects will be prompted to summarize their background IP before start of the Testa Challenge Weeks.

Selected projects are expected to actively participate in the planning phase, starting February 2022. An experienced Testa Center specialist will work together with your team 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 parts of the Testa Challenge Weeks. 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 Weeks, 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*. Please note that travel and accommodations are not included, and that we will charge a **no-show fee of 20 000 SEK** (not applicable if travel restrictions due to Corona pandemic are 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 science. The Challenge is funded by Region Uppsala and Tillväxtverket through the European Regional Development Fund and supported by Cytiva.

** Given that your company is eligible for de minimis aid*

Welcome with your application!

To apply for Testa Challenge 2023, download the application form at www.testachallenge.com

We are here to help you with your application and are happy to give you feedback on your proposal. To ensure feedback, make sure to send in your application no later than October 12th, 2023, at 22:00 CET.

The deadline for the final project proposal is October 25th, 2022, at 22:00 CET.

Questions? Do not hesitate to contact us!

We are more than happy to answer all your questions, please contact malin.wiederholm@stuns.se

Testa Challenge is made possible thanks to

cytiva

STUNS life science

Region Uppsala

EUROPEAN UNION
European Regional
Development Fund

TestaCenter
In collaboration with Cytiva

PALL
PALL CORPORATION

Swedish Agency
for Economic and
Regional Growth

Appendix 1 –Technology Readiness Levels (TRLs)

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.