

Do you catch yourself wondering how to move your *in vitro* NAM from the lab to industrial production?

Well, wonder no more! Take a seat while we guide you through 5 expert tips to transform your animal-free science into a successful enterprise.

The fact is: industries are replacing animal testing with NAMs...at an increasing rate.

The global non-animal alternative testing market is growing. It will reach a value of USD 1.65 billion by 2023.

Now some more details. In the last decade the use of animals for scientific purposes has been largely reduced (22% in the EU alone!). Scientific breakthroughs and regulatory paradigm shifts are key ingredients in this transition.

Do you know that thirty years ago, there were hardly any recognized tests based on NAMs? HARDLY ANY. A lot has changed since then. Currently, there are 49 NAMs included in OECD test guidelines. In addition, *in vitro* testing for skin sensitization and eye irritation has been made default by REACH EU and for about a decade, cosmetic testing in animals is banned in several regions.

A truly human and humane revolution!

Now, you might be asking: *Why should I take advice from this blog?*

Fair question. Please allow us to introduce ourselves. We are a German OEM. We manufacture plastics and membranes for off-the-shelf and customized life science products.

We also produce and commercialize our own NAM product – cellQART® Cell Culture Inserts – and we are beyond excited to be part of the 3Rs transformation.

We have been around for long, long years...60 to be precise. Through this time, we have collected invaluable knowledge. Today, we would like to share with you what we have learned. Pleased to meet you and thanks for stopping by!

Without further comment, let's look at the tips we have prepared for you.

✓ Tip # 1: Identify the unmet needs

According to Prof. Mark Ferguson from the advisory board of the European Innovation Council, the biggest challenge to turn your science into a business is the understanding of your customer needs.

The industrial production of a NAM demands time and resources. It is *fundamental* to evaluate the added benefit and future demand of your product. This must happen during the early conceptualization stage.

In other words, you should reflect on what is the unique selling point of your NAM and what are the current unmet needs that it will fulfill. These will assure the proper evaluation of the product, preventing the misuse of resources where there is no significant benefit or demand.

Our advice. Listen attentively to the final user. Design polls. Join NAM groups – or even better – build up a group. Attend scientific meetings. Remain open and flexible. And why not, create your own scientific advisory board!

✓ Tip # 2: Keep an open communication with all stakeholders

“Good communication is the bridge between confusion and clarity”

Whereas significant scientific progress has been made in the NAMs field, there are communication hurdles that are necessary to address to make from these alternative approaches THE new sustainable standard.

We have identified a strong need to improve the communication between all stakeholders, including but not limited to:

- 🔗 Scientists
- 🔗 Industrial suppliers
- 🔗 Testing centers
- 🔗 Big pharma
- 🔗 CROs
- 🔗 Regulatory bodies
- 🔗 Non-profit organizations

Several forums and consortiums have been created to overcome this issue. These channels facilitate communication between stakeholders and serve as invaluable point of contact for collaborations. Here are some resources that we find very useful:

- 🔗 Altertox. <https://academy.altertox.be/>
- 🔗 Dutch Transition Programme for Innovation without the use of animals. <https://www.transitieproefdiervrijeinnovatie.nl/>
- 🔗 IQ Consortium for Microphysiological systems. <https://www.iqmeps.org/>
- 🔗 OpenTox association. <https://opentox.net/>
- 🔗 National Centre for the Replacement, Refinement and Reduction of Animals in Research <https://www.nc3rs.org.uk/>
- 🔗 Center for Alternatives to Animal Testing – Johns Hopkins Bloomberg School of Public Health <https://caat.jhsph.edu/>

Join them, you won't regret!

✓ Tip # 3: Consider the final product requirements

This is important.

From the very beginning, we advise to think on the requirements of your initial industrial prototype. By doing this, you will save invaluable amount of time and resources.

When all the functional and non-functional requirements are defined from the beginning, you will prevent unnecessary project iterations.

But, no worries!

To make things easier, we have compiled a list for you.

When designing your NAM, have in mind the following points:

- (a) Material selection and tolerance levels to comply with biological evaluation according to applicable standards
- (b) Regulatory strategy and standards
- (c) Environmental conditions, packaging, labelling and transport profile
- (d) All critical quality parameters affecting homogeneity of cell growth to enable reproducible results
- (e) Quality control and product acceptance levels
- (f) Objective measures to prove successful verification of requirements
- (g) A well-balanced interaction of ergonomics, appearance, functionality, technology, and ecology

✓ Tip # 4: Engage with established manufacturers and industrial partners

Quality.

Quality is the nature of the game.

When your final goal is to bring your science to the market, a fundamental aspect is to achieve a reproducible production. We could not emphasize this more.

This will have an impact on the final acceptance of your NAM.

Quality is related to the ability to generate consistent and uniform results. A key parameter is the design and building of production tools. These are the basis to produce high quality complex components in large quantities.

We are aware that the industrial production of NAMs could sound like a mysterious operation. Thus, we would like to give you an idea on how the process looks like.

Let's imagine you approach us. You have a NAM concept containing plastics and membranes to support cell growth. First, as highly integrated and mature manufacturer, we will have a close dialogue with you. We will identify your needs and requirements. Based on them, we will develop specific plastic molding solutions and PFOA-free membranes. We will then guide you through all the potential design options with affordable prototypes. Next, we will develop final specification parameters in an agile way. Once the final stipulation has been released, we will build the assembly machinery and injection molds. We will then perform a validation process and the manufacturing ramp-up can start. Unlike requirements characterizing the product, during the process validation, the final production parameters are defined as a result of a design of experiments (DoE).

To ensure the highest quality of your NAM at larger volumes, it is important to select an industrial partner with a strong reputation for each of the single components and their assembly into a final product.

Now, we will get more specific. We would like to talk to you about a successful example of product development: our off-the-shelf brand cellQART®, Cell Culture Inserts.

Cell culture inserts are composed by a plastic support and a semipermeable membrane. They are ideal to grow cells in an *in vivo* like environment. They allow cells to receive nutrients from the apical and the basolateral side. Cells couldn't be happier! Some of the applications include tissue barrier modelling, co-cultures, organoids, migration and invasion assays, among others. Our inserts are currently used by academic labs all over the world, as well as contract research organizations, cosmetic, toxicology and drug testing centres.

To guarantee that cells grow as required on the inserts, the ability to control all the quality parameters is an essential feature. For example, each section of the semiporous membrane – that serves as support for cell growth – must have the same pore size distribution. The membrane must be appropriately coated and evenly welded to the plastic. If any single element is defective, the whole cell culture will be damaged. Consequently, these aspects are crucial. We rigorously monitor all the parameters in our end-to-end checking process. The development of our cell culture inserts was only possible as our highly qualified team of biologists, chemists and product developers, as well as our plastic and membrane production are located at the same site.

We feel proud to contribute to reducing the number of animals used for scientific procedures and we will keep working towards this goal, based on ethics and quality.

5 tips to turn your *in vitro* NAM into a business

From concept to completion:

✓ Tip # 5: Keep doing the good job!

As Andrew Wheeler, JD, MBA, Administrator of the Environmental Protection Agency said:

“We can protect human health and the environment by using cutting-edge, ethically sound science in our decision-making that efficiently and cost-effectively evaluates potential effects without animal testing.”

The aim is to develop more powerful, reliable, and financially self-sustainable methods that mimic the complexity of higher organisms.

Finally, the goal to reduce, refine and replace animal testing is as important for the animals as it is for us.

By developing standardized human relevant NAMs of industrial interest, it would be possible to improve the assessment of chemicals and cosmetics, reduce drug development failure rate, advance human benefit, and protect animal welfare. Let's keep working to achieve these goals!

Now, want to hear the greatest tip of them all?

Partner with us!

By partnering, we could progress!

We bring innovative, high-quality products to market acceptance – always in compliance with the regulatory provisions.

As an OEM supplier, we produce in accordance with the requirements of the GMP and ISO 13485 in controlled areas or clean rooms (ISO class 8). We guarantee a high availability and a secure, economic production. We are familiar with all common sterilization methods and will help you select the suitable method for your product. Our systematically designed modular research and development process, creates transparency and allows us to step in during any product development phase.

We look forward to hearing from you!

 For more information visit www.cellQART.com


 Email us at [sales \(at\) sabeu.com](mailto:sales@sabeu.com)

Follow us on:

 Twitter: <https://twitter.com/cellQART>

 Youtube: <https://www.youtube.com/channel/UCmdnGdPrdHbRERaTl1edoUA>

 LinkedIn: <https://www.linkedin.com/showcase/cellqart/>

 *Karina Cuanalo-Contreras, PhD has more than 10 years of experience in cell culture and works as cell biology specialist at cellQART® by SABEU GmbH & Co. KG. SABEU offers off-the-shelf cell culture inserts and project based customization with 100 % inhouse production of plastics & membrane components.*