

Keeping Pace with Increasing Complexity in Pharmaceutical Analytics

Founded in 1995 in response to a growing need for outsourced pharmaceutical stability testing, A&M STABTEST has developed into a broad analytical service provider. In this interview with The International Pharmaceutical Industry Journal, the company looks back at its origins and discusses how increasingly complex drug products, inhalation therapies, new analytical technologies and digitalisation are changing the requirements for pharmaceutical analytics.

Please introduce A&M STABTEST. How was the company founded, and which analytical testing services does the company provide to the pharmaceutical industry today?

The story of A&M STABTEST began with four analytical scientists who studied together at the University of Cologne and later worked in the pharmaceutical industry, gaining first-hand experience of its analytical and regulatory requirements. In the early 1990s, new ICH guidelines and increasing post-authorisation requirements created a growing need for stability testing, while external capacity remained limited. The four scientists recognised this gap and, in 1995, founded A&M STABTEST as one of the first German GMP-certified provider to offer pharmaceutical analytics and stability testing as a strategic outsourcing solution.

GMP has been at the core of the company from the beginning. A&M STABTEST has been GMP-certified since its foundation and is operating in an international regulatory environment since many years, including regular inspections by the EMA, the FDA and other regulatory authorities.

From these beginnings, the company has developed considerably. Today, A&M STABTEST employs nearly 400 people across two sites in Bergheim and Mainz and provides analytical services along the pharmaceutical product lifecycle. Our work ranges from API and excipients testing through process performance qualification (PPQ) to finished pharmaceutical products and combination products. It also includes packaging and drug-device testing, including extractables

and leachables, material characterisation, container closure integrity and functional testing.

Our scientific scope has expanded accordingly. In addition to classical pharmaceutical analytics and stability testing, we provide analytical method development, transfer and validation, quality control and release testing, mass spectrometry, bioassays, biopharmaceutical characterisation and specialised inhalation analytics. We work with classical small molecules as well as biological molecules, complex formulations and new therapeutic approaches.

For us, development is therefore not simply about adding laboratory space or new instruments. It is about continuously building the analytical capabilities and specialist expertise required as pharmaceutical products and regulatory requirements become more complex.

What sets A&M STABTEST apart? How does the company differ from other analytical service providers?

A characteristic of A&M STABTEST is the combination of scientific expertise, flexibility and personal communication. We are large enough to offer a broad analytical portfolio and support complex projects in a regulated pharmaceutical environment. At the same time, we have maintained direct communication structures.

For our customers, this means that they are not simply sending samples to a laboratory and receiving results some weeks later. They communicate directly with the scientists involved in their projects.

This becomes particularly important when something does not work as expected – and in pharmaceutical development, this can always happen. In such situations, you need more than an analytical result. You need people who understand the method and the product and who can discuss possible solutions with you.

Another important aspect is specialist knowledge. Particularly when dealing with unexpected results or working under

time pressure, a good understanding of the customer's regulatory requirements is essential. Many of our employees have been with A&M STABTEST for many years, building extensive knowledge of specific products, analytical methods and their history. This experience allows us to assess unexpected results in the appropriate context and provide the analytical support required.

For us, good service therefore means more than generating GMP-compliant data. We also want to understand why an analysis is needed, which question has to be answered and how the results will be used.

What are the key analytical challenges associated with testing dry powder and metered-dose inhalers, and how do you help customers address them?

Inhalation products are particularly interesting from an analytical point of view because you are not only analysing the formulation, but also the performance of the complete drug-device combination.

For both dry powder inhalers and metered-dose inhalers, parameters such as Aerodynamic Particle Size Distribution (APSD), and Delivered Dose (DD) are essential. It is not sufficient to determine how much active pharmaceutical ingredient is present in the product. You also need to understand how the dose is delivered, which particle sizes are generated and whether this performance is reproducible.

With DPIs, for example, airflow plays an important role because the patient's inspiratory effort contributes to the dispersion of the powder. MDIs have different challenges, particularly regarding consistent aerosol generation and dose delivery. Each inhalation system therefore has to be understood and tested according to its specific characteristics.

The analytical procedures themselves are also demanding. Cascade impaction requires specialised equipment, several analytical steps, controlled environmental conditions and, most importantly, experienced analysts.

For this reason, we have invested in the necessary instrumentation as well as

dedicated inhalation laboratories with controlled temperature and humidity conditions. However, having the right equipment is only one part of it. You also need people who perform these analyses regularly and understand the critical parameters of the method and the product.

You can buy an instrument quite quickly. Building the necessary experience takes years.

What trends are currently shaping the development of inhalation therapies, and how are they influencing analytical testing requirements?

One interesting development is that inhalation is no longer only associated with classical respiratory indications such as asthma or COPD. The lung is increasingly being considered as a route for more complex therapeutic molecules. We see growing interest in nanoparticle-based formulations, biological molecules and nucleic-acid-based approaches, for example LNP-formulated mRNA and DNA.

From an analytical perspective, this makes the situation much more complex. Classical inhaler performance testing remains essential. We still need to understand Delivered Dose and aerodynamic particle behaviour, but these tests increasingly have to

be combined with advanced characterisation of the formulation and the active substance.

As a result, different analytical areas are coming closer together. Aerosol science may need to be combined with mass spectrometry, particle characterisation, biological assays or other specialised technologies.

At the same time, there is greater focus on the device and packaging components that are in contact with the pharmaceutical formulation. This means that extractables and leachables are becoming increasingly relevant, together with other aspects of packaging and device testing such as material identification and characterisation, container closure integrity and functional testing.

This shows that inhalation analytics is becoming increasingly multidisciplinary. It is no longer only about testing aerosol performance, but about understanding the formulation, the device and their interaction as a complete system.

How does A&M STABTEST ensure it consistently meets the quality expectations of customers and the requirements of global regulatory authorities?

For a pharmaceutical analytical service provider, quality as well as trust and confidence are fundamental. Our customers

rely on our data for regulatory submissions, batch release and other important decisions. They therefore need confidence not only in the results, but also in the processes and people behind them.

Our laboratories operate according to current GMP requirements, applicable regulatory guidelines and customer-specific requirements. We also have many years of experience with regulatory inspections and customer audits, including repeated FDA inspections.

However, compliance alone does not create trust. Customers also expect reliable timelines, transparent communication and scientifically sound investigations when unexpected results occur. This requires experienced scientists who understand the method, the product and its regulatory context. Many of our employees have worked with certain methods and customer products for many years, building specialised knowledge that can be particularly valuable when assessing unusual results.

For us, quality therefore combines regulatory compliance, scientific expertise and reliable processes. Together with open communication, these elements create confidence in our work and the long-term trust required between a pharmaceutical company and its analytical service provider.



How is A&M STABTEST continuing to develop its analytical capabilities?

We grow with our customers. We listen closely to their needs and follow how their products and pipelines are developing.

For us, the question is not just, "Which new instrument should we buy?" The more important question is, "Which analytical problems will our customers have to solve in the coming years?" This is what drives the development of our capabilities.

We are currently strengthening areas such as inhalation analytics, extractables and leachables – including new requirements such as USP <665> – and force measurement, while continuing to expand our capabilities for complex pharmaceutical and biopharmaceutical products.

Scientific exchange is also important for us. We organise technical workshops at our sites, bringing together customers, specialists and industry partners for presentations, demonstrations and informal exchange.

This October, our Mainz workshop will focus on OINDP testing and inhalation analytics, co-hosted by Copley, while the Bergheim workshop will cover advanced protein characterisation, co-hosted by Bio-Techne/R&D Systems.

These are not intended as sales events. They provide an opportunity to discuss technologies, practical applications and real analytical challenges. At the same time, the exchange helps us understand which capabilities our customers may need from us in the future.

What does the future of the company look like?

We want to remain a reliable analytical partner for our customers as their products

and analytical requirements become more complex. Quality control and stability testing will remain important parts of our business, while we continue to evolve with the market and develop areas that require specialised infrastructure and scientific expertise.

Inhalation is one example. As more complex therapeutic modalities are developed for pulmonary and nasal delivery, we can combine established OINDP testing with advanced analytical technologies to address the resulting analytical challenges.

Digitalisation is another important topic. We have started a long-term project that will gradually bring our complete operations into one integrated system. It is not simply about replacing paper with electronic documents, but about connecting processes and data across the company. In a GMP-regulated environment, this transformation has to be carefully planned, validated and implemented step by step.

We are therefore developing A&M STABTEST on several levels at the same time – scientifically, technologically and operationally.

Finally, you came to A&M STABTEST from a different professional background. How does this influence your role in Business Development?

That's right. I'm a trained molecular biologist, and before joining A&M STABTEST I spent 15 years in product sales and the management of service projects in life science research. Moving into pharmaceutical analytics meant entering a new and highly regulated field, but my scientific background and commercial experience provide a useful perspective for my responsibilities at A&M STABTEST.

Business Development at A&M STABTEST is mainly strategic. We analyse developments

in the pharmaceutical market, follow new technologies and therapeutic trends, monitor the competitive environment and identify areas where A&M STABTEST should further develop its analytical portfolio. Another important part of our role is positioning the company in the market and representing A&M STABTEST within regional and wider life science and pharmaceutical networks.

For me, this combination makes pharmaceutical analytics an exciting market to work in. I enjoy the exchange and collaboration with our customers and industry partners, and I look forward to the new challenges and opportunities the coming years will bring.

UPCOMING WORKSHOPS

A&M STABTEST Technical Workshops 2026

07+08 October, Mainz: **OINDP Testing & Inhalation Analytics** – co-hosted by Copley

Further information and registration:

<https://events.am-labor.de/mz/workshop/07-08.10.26>

15 October, Bergheim: **Advanced Protein Characterisation** – co-hosted by Bio-Techne/R&D Systems

Further information and registration:

<https://engage.bio-techne.com/amstabtest>



**Dr. Regina
Ohmer**

Dr. Regina Ohmer joined A&M STABTEST's Business Development team in 2025, following 15 years in the life science industry, including positions at Tebubio and Singleron. Her experience covers customer-focused business development, project management and marketing, and she represents A&M STABTEST in regional and international industry networks. A trained Biological Technical Assistant, she holds a PhD in Molecular Genetics from the University of Cologne.

