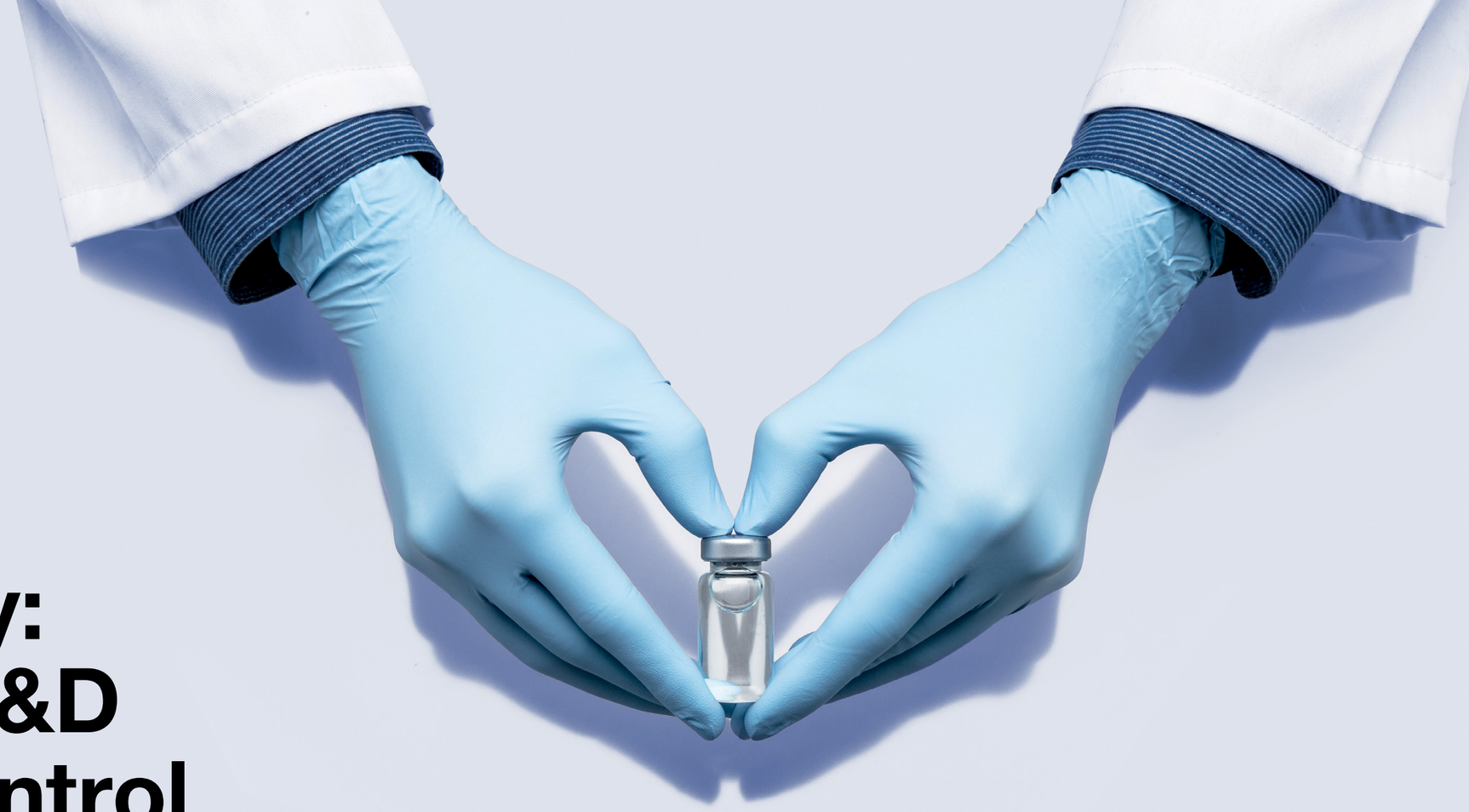
Anton Paar

Vaccine Analysis

Product Portfolio



The Safest Way: Solutions for R&D and Quality Control of Vaccines

Vaccines are one of modern medicine’s great success stories, from smallpox to SARS-CoV-2.

For therapeutic use, a vaccine must be carefully developed and equally thoroughly analyzed at every step of the formulation and production process before it is administered.

A simple jab prevents life-threatening diseases. In the same way, dedicated measuring solutions, along with advanced technical and software features, prevent inaccuracies and errors that can reduce the effectiveness, safety, and extremely high quality of these biopharmaceuticals.

Anton Paar develops and provides solutions for vaccine development, formulation, and quality control, including for the analysis of active agents, excipients, and final product formulations.

Find out more

Vaccine Analysis

The process of formulating vaccines, regardless of the specific active agent, is critical to ensure vaccine efficacy and stability throughout storage, distribution, and delivery.

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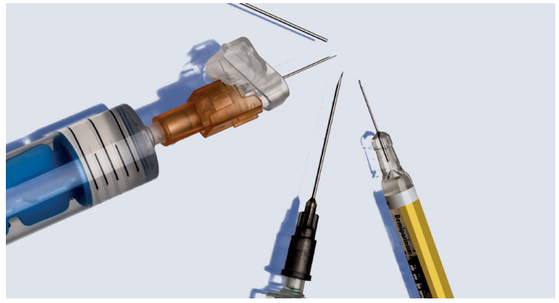

Injectability
A key aspect of vaccine delivery is comfort during the injection. Developing a vaccine formulation that maintains viscosity low enough that it can be easily delivered with a syringe is key. Many vaccine formulations comprise a highly viscous liquid that is difficult and painful to inject. Thus, analyzing vaccine formulations for their viscosity is a necessary step in both vaccine formulation development and quality control.

Vaccine safety, compliance, and dosage consistency
Incoming goods and final product formulations must be analyzed to ensure consistent quality parameters, such as density, refractive index, specific optical rotation, clarity, and concentration. This ensures a safe and effective product.

Quality-control determination of these parameters using Anton Paar's multiparameter measuring systems helps avoid contamination and satisfies pharmacopeia requirements. Anton Paar's industry-leading array of laboratory instruments – with convenient modularity – provides extremely accurate, highly reliable testing.

Vaccine stability
Controlling the charge of liposomes is critical to ensure that they remain suspended rather than aggregate. Electrophoretic light scattering (ELS) can be used to determine the zeta potential of liposomes, helping to assess whether the vaccine formulation will remain electrostatically stable throughout its shelf life, transport, and delivery.

mRNA/liposome-based vaccines
mRNA-based vaccines are often formulated in a lipid-based liposome carrier that helps to protect the RNA from RNA-cleaving enzymes. They also assist in delivering the mRNA molecules into the target cells.

Ensuring consistent liposome size is critical when formulating vaccines. Dynamic light scattering (DLS) is a useful technique for measuring the size and size distribution of liposomes, helping to confirm that the liposomes in the formulation are consistent in size and stable over time.

Data integrity following ALCOA+ principles
Vaccine production must conform to stringent pharma regulations on data integrity, traceability, and compliance, including 21 CFR Part 11 and ALCOA+. This requires structured collection, management, and review of measurement data, as well as of metadata from quality control and batch release.

AP Connect securely centralizes laboratory instrument data, enables digital, error-free data flow, and supports audit trails and review and approval workflows. Dedicated Pharma Edition features help ensure compliant, transparent, and traceable laboratory operations.

Vaccine Safety, Compliance, and Dosage Consistency

Key parameters for final quality control, batch release, and dosage consistency

Challenge:
There has been a lot of research into new vaccines. To ensure a safe and effective product, thorough final quality control and batch release checks have to be performed. Measurements need to be fully traceable and comply with international regulations and guidelines.

Solution:
Anton Paar's density meters and viscometers support quality control by enabling easy, reliable assessment of key vaccine parameters such as density and viscosity.

Benefits:
All instruments offer a combination of a simple user interface and technological and software features to eliminate measurement errors. Modular extensions and automation possibilities are available. Measurement methods comply with pharmacopeial requirements.

Instruments:

- **DMA 4002 / 5002**
- **Lovis 2001**
- **Abbemat Pharma series**
- **MCP polarimeter series**
- **ViscoQC 300**

Checking turbidity as an indicator for product contamination

Challenge:
Buffers and saline for vaccine production and, of course, the final vaccines have to be checked for turbidity, which is a potential indicator for contamination.

Solution:
Check turbidity with a multiparameter measuring setup based on a density meter as the master instrument, with the option to add modules such as the Haze 3001 turbidity measuring module.

Benefits:
Perform turbidity measurements with simple handling and without scratch-sensitive measuring cuvettes or calibration. The pharma compliance features of an Anton Paar density meter as a master instrument, together with its software solutions, ensure compliance and traceability for each measurement.

Instruments:

- **DMA 4002 / 5002 / 6002 + Haze 3001**

Vaccine Stability

Vaccine particle size and surface charge affecting product formulation, safety, and stability

Challenge:
Monitoring the particle size and surface charge of vaccine formulations during R&D, production, transportation, and storage is critical to ensure a safe and effective vaccine.

Solution:
DLS measurements with Litesizer DLS series permit quality control of antiviral vaccines, while ELS measurements generate more insight into their aggregation behavior.

Benefits:
Size and surface charge measurements of vaccines enable comparisons of different formulations, as well as analysis of the vaccine response to heat, transport, and agitation, and assessment of overall formulation stability and purity. The zeta potential provides an indication of the stability of the vaccine formulation.

Instruments:

- **Litesizer DLS 301 / 501 / 701**

Influence of variable environmental conditions on vaccine stability

Challenge:
The stability of vaccines and vaccine components under variable conditions during transportation and storage is crucial.

Solution:
Examine the integrity and aggregation behavior of the final product in response to cold chain disruptions with Litesizer DLS. For components, perform homogeneity checks on in vitro-transcribed RNA, and conformation and aggregation behavior checks for recombinant antigens between production steps.

Benefits:
Produce an effective vaccine and safely deliver it to patients.

Instruments:

- **Litesizer DLS series**

Injectability

Viscosity checks of the sample to ensure injectability and administrability

Challenge:
The viscosity of the injectable must be correct to guarantee injectability of formulations. Whereas low-viscosity injections are perceived to be more painful than higher-viscosity injections, overly viscous formulations can lead to occlusion of the injection system, making it difficult to complete the injection.

Solution:
Measure viscosity at multiple shear rates and speeds with ViscoQC 300 or Lovis 2001. Analyze the flow behavior of the sample and use the results to optimize viscosity, ensuring proper administration.

Benefits:
ViscoQC 300 features, including digital automatic spindle and guard detection and V-Comply software, ensure correct viscosity measurement. Lovis 2001 has short measurement times and sample volumes of only 0.1 mL. Both systems conform to 21 CFR Part 11 regulations and pharmacopeia.

Instruments:

ViscoQC 300

Lovis 2001

How shear forces affect vaccine stability

Challenge:
If the high forces that occur during vaccine injection are not measured and controlled, they can cause degradation or aggregation of the active agent in the vaccine formulation, potentially triggering an immunogenic response.

Solution:
Anton Paar's MCR directly measures how the shear forces that occur during an injection affect the structural and flow properties as well as the overall stability of vaccine formulations.

Benefits:
Accurately characterizing how a vaccine formulation responds to the shear stresses that occur during injections helps detect and avoid injection-induced aggregation or degradation of the formulation. This ensures a safe and complete dose for each patient.

Instruments:

MCR rheometer series

mRNA/Liposome-Based Vaccines

Formation and stability analysis of liposomes

Challenge:
Many vaccines are formulated within liposomes. Care must be taken during the formation and processing to ensure that they are similar in size, remain in the nanometer size range, and stay stable during packaging, transport, and delivery – as there is a risk that they may combine to form multi-layer vesicles, rendering drug delivery ineffective.

Solution:
The Litesizer DLS particle size analyzer is an excellent tool for tracking and optimizing liposome formation, as well as monitoring liposome size and stability under different processing conditions, such as temperature and pH. DLS and ELS are used to measure liposome size and zeta potential, respectively, providing key indicators of formulation stability.

Benefits:
Exact characterization of liposomes optimizes formation conditions and allows monitoring of size and stability over time and under a range of different storage and handling conditions. This supports the development and manufacturing of highly targeted drug delivery particles in vaccines.

Instruments:

Litesizer DLS 301 / 501 / 701

Data Integrity Following ALCOA+ Principles

Best practices for data management

Challenge:
Vaccine quality control generates large volumes of measurement data and metadata. Ensuring complete traceability, preventing transcription errors, and meeting ALCOA+ and 21 CFR Part 11 requirements is challenging in paper-based or fragmented digital workflows.

Solution:
AP Connect automatically collects measurement data from connected instruments and stores it centrally. Results and metadata are structured consistently, creating a single, reliable, and secure source of laboratory data across workflows.

Benefits:
AP Connect establishes best practices for laboratory data management by centralizing measurement data and metadata in a single digital system. Automated data capture reduces manual handling and errors, while structured data improves availability, consistency, and reuse.

Instruments:

AP Connect Pharma
(integrates 100+ Anton Paar instruments and 250+ instruments from other vendors)

Electronic signatures: check, review, and approval

Challenge:
Paperless laboratory processes require controlled checks, reviews, and approvals of data generated across instruments, teams, and labs. Without clear responsibility, data may be reviewed by the wrong person or shared unintentionally, putting data integrity and compliance at risk.

Solution:
AP Connect supports flexible electronic-signature workflows. Review steps can be performed on the instrument, in AP Connect, or in a combined process. The Labs feature enables data segregation, ensuring clear separation of duties across teams and laboratories.

Benefits:
Flexible review workflows, lab-based data segregation, and centralized audit trail review in AP Connect establish a clear chain of responsibility. This strengthens data integrity, supports ALCOA+ and 21 CFR Part 11 compliance, and simplifies regulatory inspections.

Instruments:

AP Connect Pharma
(integrates 100+ Anton Paar instruments and 250+ instruments from other vendors)

Accurate. Traceable. Compliant.

Find out more

Comprehensive qualification protocols ensure traceability and regulatory compliance while minimizing operational downtime and resource use.

Audit readiness
With Anton Paar, you are always ready – whether for internal purposes or for an external regulatory audit. You are guided step-by-step to full documentation.

Qualification services
Your instrument comes with a comprehensive qualification package that goes far beyond a regular installation.

Maximum uptime
Anton Paar's compliant preventive maintenance documentation ensures a clear risk assessment to prevent non-compliance, supports adherence to 21 CFR Part 11, follows regulatory guidelines such as the FDA 4Q model, and guarantees that all service activities are performed in accordance with GMP requirements.

Our well-trained and certified technicians are ready to keep your instrument running smoothly.
Maximum uptime | Warranty program | Short response times | Global service network

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