



Marburg, Germany



SITE HEAD

Anne Katrin Hilbert
Managing Director

Our Marburg laboratory has cutting-edge expertise in tailored, functional, and immuno-binding serological assays for vaccine licensures, with a staff of about 90 specialists. We have more than 20 years of demonstrated expertise in selecting, developing, and validating immunological assays in support of vaccine development in global R&D environments.

Key abilities

- All clinical serology services
- Broad range of immunochemistry and functional assays, with a focus on:
 - Neisseria meningitidis serobactericidal assays
 - Opsonophagocytosis assays
 - Virus neutralization assays
 - Hemagglutination inhibition assays
 - Multiplex ELISA assays

Laboratory

- 25,000-square-foot BSL-2 labs and offices
- 750-square-foot BSL-3 labs
- Annual sample testing capacity: 200,000
- Sample storage capacity: 1,000,000
- Operate under GCLP and EHS standards
- Human sample management and storage:
 - Dedicated sample logistics group
 - Automated tube labeling (Scinomix) and aliquot generation (Tecan)



Quality framework
GCLP

OUR STORY

1904

Foundation of the "Behringwerke" site in Marburg, Germany by Emil von Behring using the prize money for being honored with the first Nobel Prize in medicine on his discoveries of a diphtheria antitoxin.

The primary focus on vaccines extends over time to blood and plasma products (now CSL Behring) and diagnostics (now Siemens Healthcare) in conjunction with the company changing hands multiple times. In 1994 the business areas split and Chiron acquires the vaccine business.

1998

As part of Chiron Vaccines, a human serology lab is established in Marburg with 10 people. In 2001 the first clinical lab data are generated using antigen-binding (ELISA) and neutralization assays to support the licensure of a TD-IPV vaccine. Over time, there is expansion to add expertise in meningitis and influenza serology for vaccine development.

2006

Novartis takes over the entire vaccine business from Chiron, further expanding the portfolio of influenza and meningococcal vaccines. Clinical Serology becomes the central laboratory supporting clinical immunogenicity and efficacy assessments with lab data and managing the human biological samples.

2009

Clinical Serology is heavily involved in the H1N1 pandemic relief efforts. Doubling the lab team and capable of clinical testing only four months after the pandemic is announced to allow rolling submission of clinical data for quick vaccine licensure.

2010

FDA inspection held in Clinical Serology on the meningitis serum bactericidal assays used for licensure of a MenACWY vaccine and successfully passed.

2012

Lab business increases in size and broadens in scope, adding a dedicated sample management and a business operations team, covering all clinical trial-related lab work end-to-end, as Clinical Laboratory Sciences team. Investments are made in automation to increase the capacity of both the sample management and the clinical testing to support several strategic projects in bacteriology/meningitis.

2015

GSK acquires Novartis Vaccines and the clinical lab business in Marburg is fully integrated, with ISO 9001:2015 certification since 2018. Continuous improvement activities centered around assay setup, qualification, validation and performance monitoring forge close collaboration between science and the statistical teams.

2021

GSK divests the clinical laboratories in Marburg with approximately 70 employees transferring to Nexelis, with expertise to perform all aspects of assay life cycle management, including statistical evaluation. Within few months, 10 positions are added in order to run the Nexelis labs as an independent company on the Behringwerke campus.

2022

Nexelis joins the Q² Solutions family. Q² Solutions is a leading global clinical trial laboratory services organization providing bioanalytical, genomics, vaccines, flow cytometry, anatomic pathology, immunoassay, companion diagnostics and central laboratory services with secure, enterprise-wide biospecimen and consent management solutions.

Lab equipment and techniques

- Microtechnix Scanlab II
- Synbiosis ProtoCOL
- Luminex® FLEXMAP 3D
- SpectraMax
- Tecan Infinite 200 Pro Plate Reader
- BioTek Microtiter Plate Reader & Washer
- Scinomix Tube Labeler
- Tecan Liquid Handler & Robotic Units (EVO 75,100,200)
- Thermo Fisher Scientific KingFisher Duo Prime
- Deep Freezer Capacity (-80°C & Liquid Nitrogen)
- Clean Benchmark

About Nexelis, a Q² Solutions Company

With unrivaled expertise in immunology, five operating sites in North America and Europe, and a translational offer of services covering the needs of the pharmaceutical industry from the lead selection to the late clinical stage, Nexelis, a Q² Solutions Company, is a leading provider of assay development and advanced laboratory testing services in the infectious, metabolic, and oncologic fields. Our versatile team of scientists, working with state-of-the-art technology platforms, were instrumental in the development, qualification, validation, and large-scale sample testing of assays that supported the FDA filing of almost 350 new molecular entities, including blockbuster vaccines and biologics, anti-viral drugs, immunotherapy, gene and cell therapy products.

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Contact us

Website: www.nexelis.com

