



# Ellab Field Services and Consulting

Your journey towards a more efficient process  
and reduced operation costs starts here.

Global Expertise with Local Reach





# Ellab Field Services

Whatever you require for your qualification, validation or monitoring needs, we've got you covered. With Ellab, you get a dedicated and experienced partner for even the most challenging GMP level projects.



At Ellab, we have a global presence with local reach. Our local teams are industry experts and come well equipped with our industry leading thermal validation and monitoring equipment and the know-how to optimize your processes from start to finish.

Our engineers are dedicated to providing world-class temperature mapping, calibrations and consulting services.





## Why Choose Ellab?

We are flexible in our approach and tailor projects to your particular needs. Whatever you need to see your project through, we have it – and if you require an alternative solution, we stand ready to find the best one to ensure a successful result. Few come close to the accumulated experience and hands-on customer service that we can provide.

### Our skilled teams are...

- On standby to swiftly respond to- and tackle both your large- and small-scale projects with expert precision
- Equipped with a deep pool of relevant GMP knowledge and skills
- Experienced in using our FDA 21 CFR part 11 compliant validation, calibration and project management software
- Trained in our thermal validation and monitoring solutions

### We have...

- The most extensive global network, working with all the top 40 Life Science and Food manufacturing companies around the world
- Fleets of high-end measuring equipment for rental or service ready to go

### We strive to...

- Listen and work with our customers to find the most appropriate solutions
- Deliver global expertise with local reach through our continuously growing number of local teams across the world
- Build confidence in consumer safety, together

### Our Measuring equipment is...

- Designed and produced by Ellab for qualification, validation and monitoring purposes. We can therefore vouch for their accuracy and quality
- Produced at production sites that are ISO 14001 and ISO 9001 certified, as well as ISO 17025 accredited

# When to use Ellab

Our field services and consulting teams can be used for almost any project at any point in the process, but there are some specific scenarios in which having a team on standby really pays off:

- Unexpected projects: We are flexible and committed to meet any given timeframe
- Large projects: We are experienced at handling projects of any size and come equipped with a fleet of measuring equipment for even the most daunting tasks
- Specialized expertise: We can handle some of the most complicated projects and tasks, such as autoclaves and steam-in-place (SIP)
- Contract validation staffing/staff augmentation: We provide staff on both a short-term and long-term basis, ensuring that you have the extra hands you need at any point

## The Services we Provide

Ellab has dedicated teams for the various services we provide, ensuring that all areas are covered by capable experts. Our main lines of service can be split up into three categories:



– for on-site projects, temperature mapping qualifications and commissioning tasks



– for sparring, project management and support



– for equipment calibrations and adjustments on location



## Commissioning, Qualification and Validation Services (CQV)

Our qualification and validation teams aim to assist you with meeting industry requirements and guidelines to ensure safe and high-quality products. We cover a wide array of applications and tasks, from all kinds of temperature mapping, IQ, OQ and PQ's to alarm testing and shelf mapping – just to name a few. To reduce the turnaround time, we work with our efficient reporting tools, but we also accept and work with whatever report, protocol and/or SOP templates that you desire. Allowing us to draft documentation designed specifically for your project and procedures.



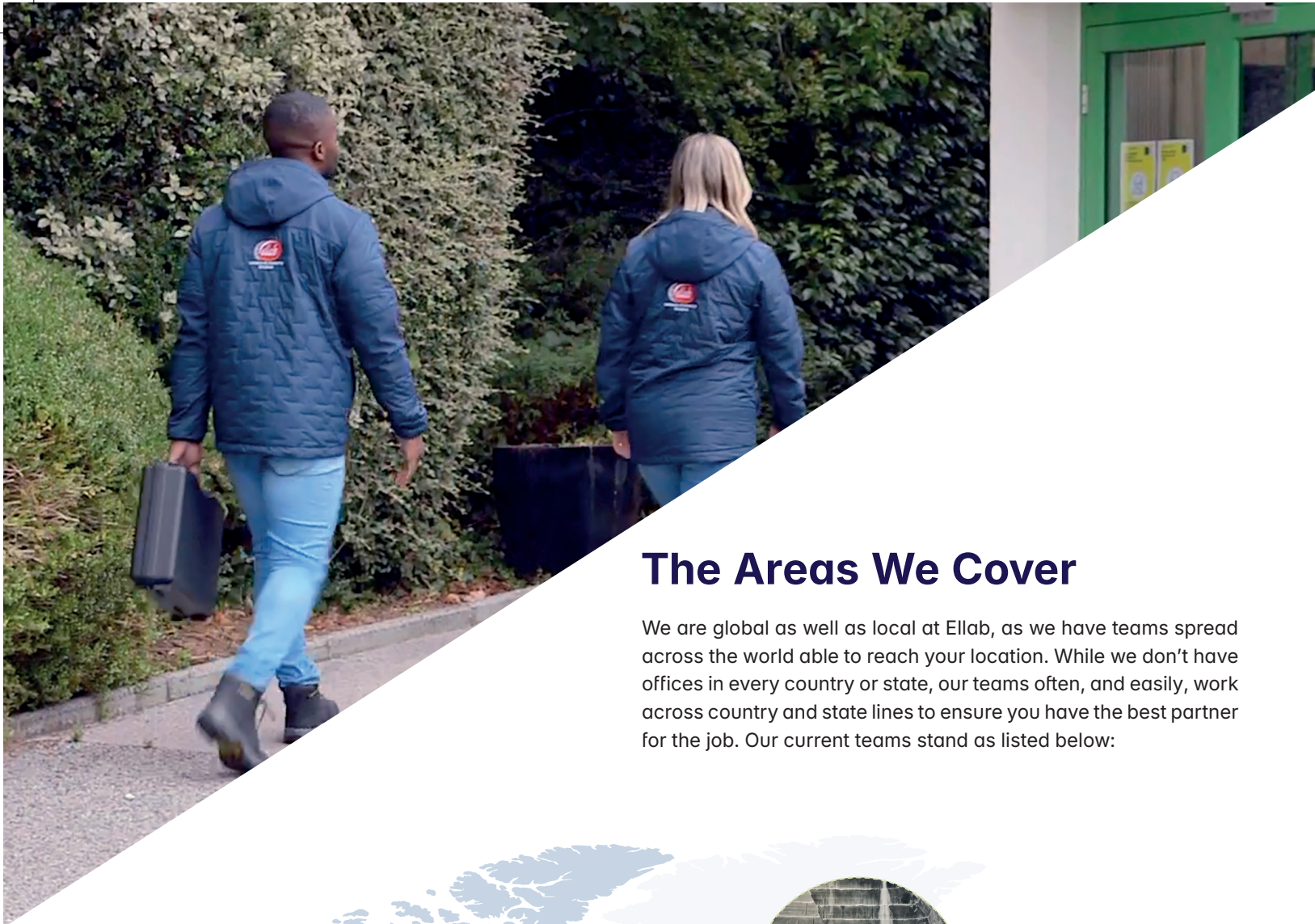
## Consulting and Engineering Services

Our consulting teams have the vast experience required to advise you on your projects and processes. All our consultants are GMP experts capable of increasing operation reliability and ensuring compliance while decreasing costs. We thrive in supporting your development and production, as well as managing your projects to eliminate deviations and bottlenecks.



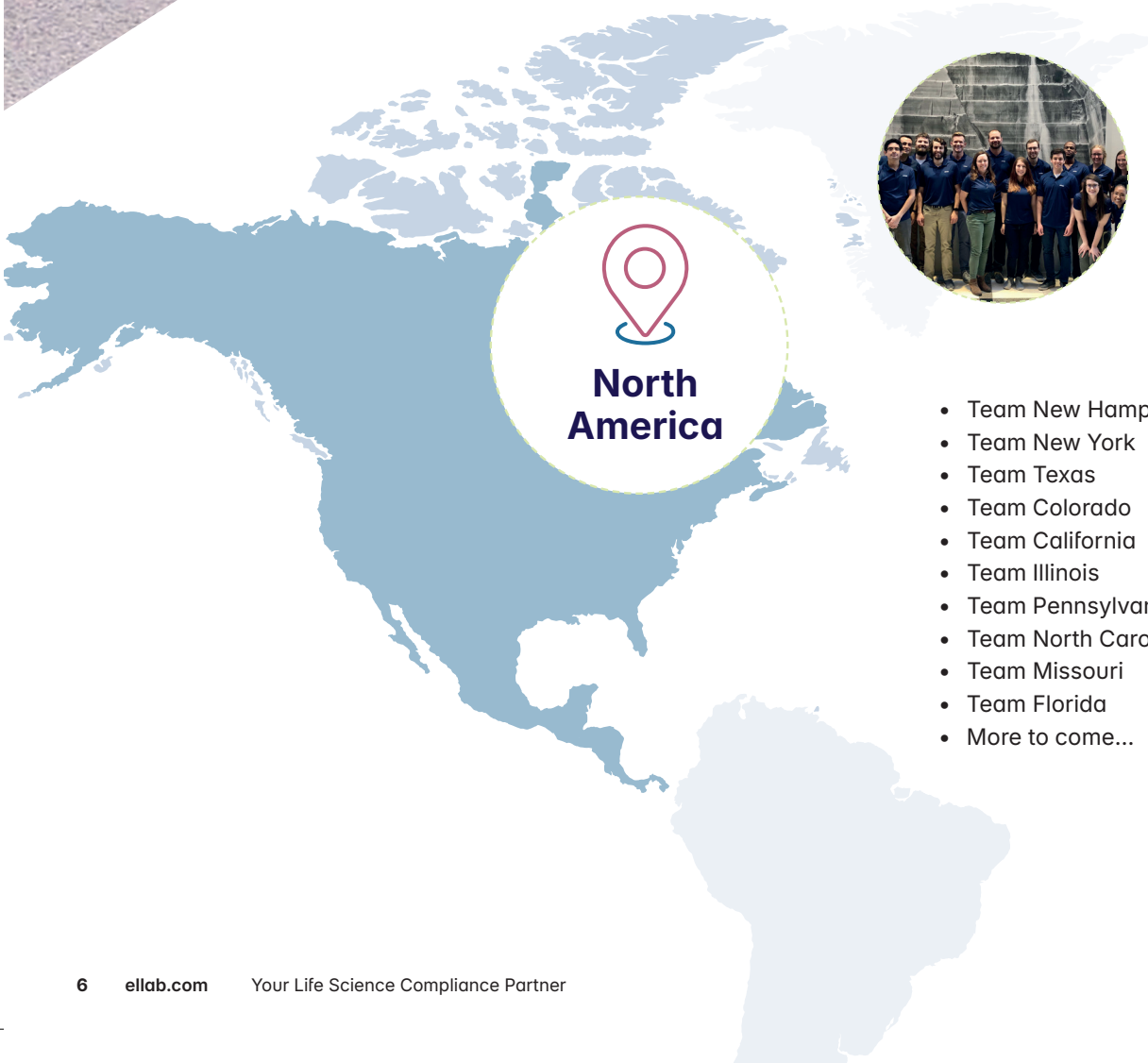
## Field Calibration Services

When off-site or factory calibrations aren't ideal, our field calibration teams stand ready to deploy to your location. With state-of-the-art calibration equipment and software, we provide efficient calibrations of your crucial measuring equipment on-site.



## The Areas We Cover

We are global as well as local at Ellab, as we have teams spread across the world able to reach your location. While we don't have offices in every country or state, our teams often, and easily, work across country and state lines to ensure you have the best partner for the job. Our current teams stand as listed below:



**North  
America**

- Team New Hampshire
- Team New York
- Team Texas
- Team Colorado
- Team California
- Team Illinois
- Team Pennsylvania
- Team North Carolina
- Team Missouri
- Team Florida
- More to come...



## Europe

- Team Nordic
- Team North Germany
- Team South Germany
- Team Switzerland
- Team Austria

- Team Ireland
- Team UK
- Team Benelux
- Team Italy
- More to come...



## Asia

- Team Philippines
- More to come...



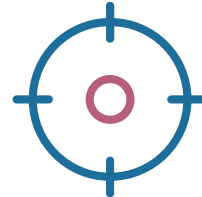
- Biotechnology
- Cell & Gene Therapy
- Contract Development & Manufacturing (CDMOs)
- Pharmaceutical
- Cold Storage Equipment Manufacturing
- Food Production
- Hospitals & Healthcare



## Qualification and Validation Services

Ellab's qualification and validation teams help you reach and maintain processes that specifically require a variety of industry guidelines and regulations. Our support ranges from the development of templates and protocols to on-site hands-on execution and management of validation projects.

Our highly trained technicians are well versed in the requirements from government agencies such as the FDA, EU and ICH, and will always document and execute projects in accordance with these bodies.

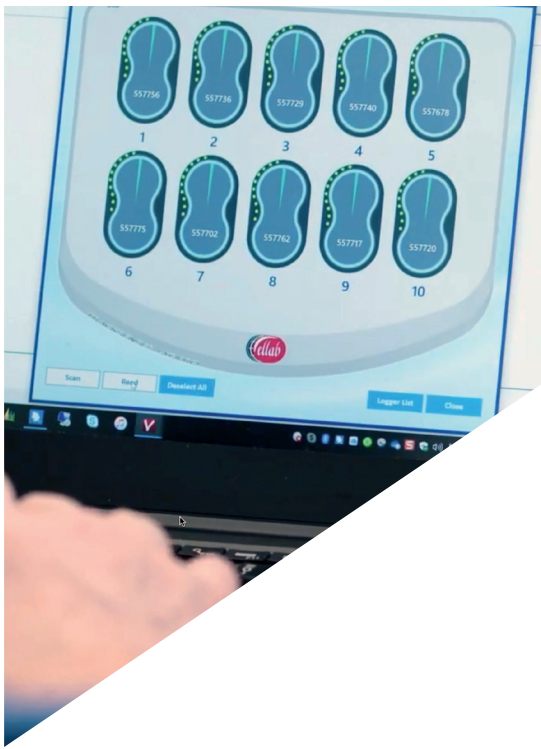


### Services Provided

Our qualification and validation services include, but are not limited to:

- Temperature mapping and environmental qualification
- IQ/OQ of validation, qualification and monitoring software
- IQ/OQ of continuous monitoring equipment
- Process calculations in combination with the ValSuite® software package
- Power interruption and loss tests
- Door open tests
- Temperature distribution tests
- Temperature penetration tests
- Alarm testing
- Loaded and empty mappings
- Sterilization mapping
- Shelf mapping
- Acceptance testing
- And much, much more...





## Temperature Mapping and Environmental Qualification

With our qualification and validation engineers, your controlled temperature units (CTU's) and controlled environmental units (CTE's) are in capable hands. We ensure that your defined storage area confidently meets certain acceptance criteria, by accurately measuring and mapping each relevant point. Our teams are well known for their efficient mapping turnaround time, while ensuring that your system is accurate and within the defined limits without excursion.



## IQ/OQ of Software

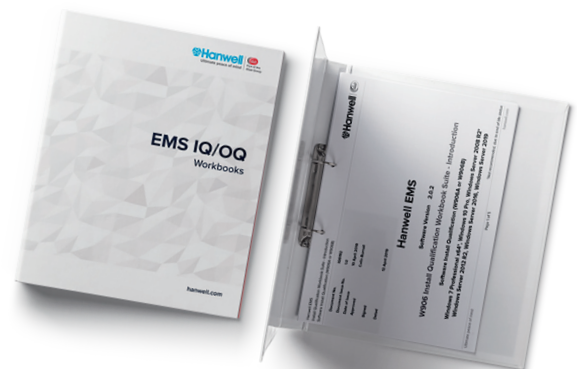
Drastically speed up the IQ/OQ of your software with the help of a capable Ellab employee. Our staff are highly experienced with both large- and small-scale IT systems, while ensuring GMP (V-Model) compliance. We provide generic IQ/OQ protocols and test plans to swiftly execute your IQ/OQ with immense accuracy.

## IQ/OQ of Monitoring Equipment

Ellab staff stands ready to be deployed to help with your monitoring installations and IQ/OQ's. We'll ensure that your monitoring hardware and software is set up to communicate appropriately and provide documentation that aligns with GAMP 5 life cycle guidelines. Additionally, our staff will save you crucial time on procedures, all while in accordance with GDP criteria.

## Reporting and Documentation

We understand the importance of documentation that meets the current Good Documentation Practices (cGDP). Our technicians and consultants are dedicated to generating accurate reports and documentation in compliance with all relevant rules and guidelines. Furthermore, any qualification and validations performed using our equipment and software include crucial calibration certificates with pre and post verification data.



# Consulting and Engineering Services

Reach the full potential of your process with Ellab's GMP consulting and engineering teams. With Ellab as your consulting partner, you get access to experts with crucial knowledge of:



- Implementing cost reduction measures
- Implementing preventative measures
- Setting up and executing master plans
- Managing project scopes, timescales and tasks
- Providing commissioning, validation or qualification reports as proof of completion
- Conducting a wide array of relevant studies, audits, assessments and tests
- Performing data analysis and error - checks
- And much, much more...

## GMP Consulting

We know how to increase operation reliability and decrease costs. Our GMP consulting experts are highly trained at providing a clear understanding of manufacturing equipment and processes, as well as translating existing and new authority requirements into clear improvements. Having an Ellab consultant on the team could prove crucial to a project's success.

## Process Engineering

Ellab's consulting and engineering teams are experts within all areas of pharmaceutical consulting and production – and we stand ready to assist you on your development and production projects with surgical precision. Our Validation Master Plans help define the scope of all projects, including the responsibilities, methods, constraints and timescale to ultimately ensure a smooth transition.

## Project Management

Our skilled project managers are dedicated to guiding you and your organization through your crucial life science projects from start to finish. We aim to eliminate mistakes and optimize your processes, all while ensuring a clear line of communication with internal and external subject matter experts. Our goal is to quickly identify bottlenecks and roadblocks to ensure an efficient and complete process.



## Field Calibration Services



Ellab's field calibration services are perfect for whenever off-site calibrations stop being an option. This could be due to the hassle of transporting sensitive measuring equipment or due to sensors being locked in crucial processes – either way, our calibration technicians have the solution. With our portable equipment, we can see to your calibrations anywhere, anytime.

Ellab exclusively uses high-end calibration hardware and software to ensure that your calibrations and adjustments are accurate and well documented. All our calibrations come with reproducible, traceable and compliant certificates that are saved to our cloud and can be printed whenever necessary.

### Additional Benefits to Field Calibrations

- Drastically reduces downtime for measuring instruments
- Eliminates shipping costs and risks
- All our calibration equipment is traceable to DANAK, NIST, DAkkS, Accredia, UKAS or equivalent body

### Typical Applications for Field Calibrations

- Control sensors on autoclaves
- Pasteurization plants
- UHT facilities
- CTU's and CTE's
- Anything within a calibration range of -80 to +400 °C

## We Always Use Industry Leading Equipment

One thing that makes Ellab stand out more than any field services and consulting provider; is that we also produce the leading qualification, validation and monitoring equipment. That means that we can vouch for the quality of the equipment and can easily handle large and specific requests. Additionally, should issues with any Ellab equipment occur, our technicians and consultants have access to an express lane of replacements or repairs.

All Ellab hardware and software is compliant with the relevant regulations and guidelines set by various government agencies, such as the FDA and EU.



### Working Together to be the Best

What has made Ellab the leading provider of qualification, validation and monitoring solutions; is our constant feedback loop between our customers and R&D – which continues to result in innovative solutions tailored for our users, by our users.

## Keep Your Consumers Safe with Ellab

Ellab provides world-leading validation, monitoring and calibration solutions and services, as well as GMP consulting, to life science and food manufacturing companies across the globe – allowing us to build confidence in consumer safety together.

We serve both small and large companies within the Life Science and Food industries and have solutions for almost all applications such as sterilization, freeze drying, environmental chamber testing, depyrogenation, warehouse mapping, pasteurization, controlled temperature units (CTU) and many more.

Ellab develops unique and innovative solutions based on input from close interactions and dialogues with our customers. Our goal is to help our customers overcome challenges and increase their productivity by providing reliable and efficient solutions.

Ellab also offers complete turn-key or supplemental rental solutions, equipment qualification and validation services and our specialized training courses within Ellab Academy.

Ellab has a long tradition and dedication for delivering the highest performance and quality in our industry. Our user friendly and flexible validation and monitoring solutions are recognized and used by thousands of customers worldwide.

Along with our customers and partners, Ellab strives to become more sustainable in everything we do. This includes complete use of green energy on our production sites, internal initiatives and sustainable R&D.

Ellab A/S in Denmark is ISO 9001, ISO 14001 & ATEX IEC 80079-34 certified. Ellab A/S Calibration facilities are accredited according to ISO 17025 by DANAK under registration no. 520 and our affiliates in UK, Germany and Italy also carry the ISO 17025 accreditation executed by local authorities.

For further information all certificates for the Ellab Group can be found here.



**YOUR LIFE SCIENCE  
COMPLIANCE PARTNER**

