
Focused
pharma
engineering
nne®

When change is the only constant, are you up to speed?

Welcome to the new pharma reality

A major shift has taken place in the world of pharma manufacturing. The days when delivering on predictable output targets and expiring patents were the biggest challenges are coming to an end. Today it's more about dealing with the growing concerns about healthcare expenditure, uncertainty of drug reimbursements and the ever-changing international quality regulations. The emergence of new drug categories – including smaller product volumes, smaller batches, orphan drugs and personalised medicine – also play an important role on the agenda of the future.

It all adds up to much greater uncertainty and a faster rate of change. Again and again, you find yourself planning for an output without knowing much about the drug, volume or deadline you're actually planning for.

Site agility:
the key to your success

In pharmaceutical operations your timelines are shrinking. The only way for you to succeed is to operate with maximum site agility and flexibility. Your facilities need to handle changes in production demands and quality regulations fast, and implement new knowledge and technology faster still.

NNE has the pharma engineering focus, expertise and experience to support you in making this happen.

In a complicated world there is no room for generalists

Focused pharma engineering

In NNE we believe that if you want to provide your customers with the best solutions, you can never become too focused or too specialised in what you do. That is why, for many years, we have been working only for the pharmaceutical industry. Today we are the world's most focused pharma engineering company, employing close to 2,000 professionals globally.

Meeting our customers' needs is our first priority. That's why we are so focused on providing you with the highly specialised expertise that enables you to manage the challenges of the new pharma reality. Through focused pharma engineering we help you obtain and maintain an optimal production so you can always deliver on demand.

THE ENTIRE MANUFACTURING LIFECYCLE

NNE delivers expert pharma engineering consultancy and services to assist you in all phases of your pharmaceutical production. We are involved in the development of new products, in the planning and establishment of pharmaceutical facilities and in the ongoing support of pharmaceutical operations. We can help you with everything from engineering design to qualification of your processes and facilities, including technology transfers. We can also help ensure that factors such as compliance, sustainability, logistics and IT systems support your process optimally. Our conceptual, basic and detailed design services include process layout, user requirement specifications and architectural concept – all with consideration for GMP processes.
We have applied our global knowledge to resolve customer tasks all over the world, and have been involved in everything from greenfield projects to expansions in numerous facilities.

GLOBAL KNOWLEDGE AND BEST-PRACTICE

Many of our employees have a background in the pharma industry. Our vast global knowledge is your guarantee of fast and future-proof solutions based on industry best practices. In short, our knowledge is your competitive advantage.

CLOSER TO YOU

We have a strong site presence, because we want to provide you with the best and most rapid solutions, so that we can help ensure your site's success. NNE can be your auxiliary arm, supporting you with a flexible additional workforce, which has the right competences and access to global knowledge and best practice. Today, a significant number of our employees are stationed permanently on our customers' sites. Through our site support programme we can act as your trusted on-site adviser, establish the right account team around you and be part of your daily operations.

BORN AND RAISED WITHIN PHARMA

Ever since Danish Novo Nordisk and German Fresenius started building pharma facilities, we have provided specialist pharma engineering skills.

With roots in Novo Nordisk and Fresenius, NNE has grown into an independent pharma engineering company with focus on serving the pharmaceutical industry.

SETTING THE STANDARD

NNE is a recognised contributor to many of the organisations that set standards in pharmaceutical quality, manufacturing and engineering as well as the guidelines produced by those organisations. We are involved in developing current standards and make our contributions through,

for example, ISPE, PDA, ASTM, ISA and ISO. We have a close working relationship with regulatory agencies and organisations such as the FDA, SFDA and WHO – and have also helped train the FDA's investigators in the FDA Process Validation Guideline.

FLEXIBLE AND RELIABLE FACILITY PROJECTS

When we deliver facility projects, we work based on a global engineering model, Our Model. This model ensures that you always get the same high quality of work

and services no matter where in the world your site is located. It also ensures that everyone on our projects works with the same well-proven methods and best practices worldwide, and they are flexible enough to adapt to yours.

Conceptual Design ▸ Basic Design ▸ Detailed Design ▸ Construction ▸ Commissioning & Qualification ▸ Handover and/or operation support

THE NNE RIPLE FORMULA FOR MANAGING THE NEW PHARMA REALITY

- Agile and flexible operations
- Seamless fulfilment of GMP compliance
- Future-proof solutions

Is it getting harder to deliver on demand?

Meet your targets with agile and flexible operations

It is getting more and more difficult for any site to deliver on demand. The constantly changing production demands, day-to-day issues, the task of keeping up production while implementing changes and ensuring regulatory compliance are just some of the challenges that threaten your product delivery. These challenges also create high-pressure periods, which push up the risk of compliance gaps and errors.

NNE can help you overcome your challenges. We specialise in making agile and flexible operations that will help you implement and accommodate changes fast so you can meet your targets.

WHY PARTNER WITH NNE?

- We have systems and standards for achieving flexible operations
- We constantly activate global best practices and expertise
- Our dedication to your plants and sites ensures fast and robust solutions
- We know how to deal with the uncertainty of the new pharma reality

BIO ON DEMAND™

Bio on demand™ is NNE's concept for a high-efficient standard facility for biopharma manufacturing based on single-use technology. It integrates flexibility by using open architecture principles for both building construction method and equipment, so it is independent of any supplier proprietary software and hardware solutions. With this concept we help you reduce investment cost and provide you with strategic flexibility.

INTELLIGENT UPGRADE

Facility expansion can be tough, and new manufacturing strategies from mergers, acquisitions and offshoring are always a challenge in existing facilities. NNE has the expertise in handling projects in fully operating plants. We can increase capacity and flexibility with minimal interruptions in your on-going production or help turn your old facilities into future business assets. Our revamp services include all activities from analysis to running production. They ensure an exceptionally short production shutdown followed by fast production ramp-up into guaranteed capacity.

OPERATIONAL AGILITY

A facility without a good organisation is useless and can fail to reach its quality and efficiency objectives. That's why NNE can assist you in establishing a good organisation, efficient operating procedures and training. With our roots in the pharma industry, we always take the specific processes of your company in to account and deliver customised training programmes that are tailored to your facility.

MULTI-PRODUCT FACILITIES

In the past, many pharmaceutical facilities were dedicated to one or a few large products. Now, more and more products are small in volume. This means there is an increased demand for highly flexible multi-product facilities – one of our areas of expertise. We can assist you in the concept, design and operation of flexible multi-product facilities – just as we have already done for many customers worldwide.

Are quality issues keeping you up at night?

Achieve seamless fulfilment of GMP compliance

Good Manufacturing Practice is a core condition in pharmaceutical manufacturing worldwide, but not an easy task. Rules and interpretations differ from country to country, and they change frequently. If quality considerations are not integrated in to your projects early enough, delays and quality issues are also certain to arise. Quality documentation and validation on the other hand demand a lot of resources.

With our certified and pharmaceutically trained professionals, NNE offers you seamless fulfilment of GMP. We have the expertise and international experience to handle the ever-more complex quality demands through GMP compliant design and solutions, the quality documentation and validation in projects.

WHY PARTNER WITH NNE?

- We are born out of GMP and have more than 25 years of experience in the field
- GMP is an integral part of the work our trained engineers deliver
- We integrate with your existing quality systems
- We apply customer-audited quality systems that support your GMP

ENSURING INSPECTION READINESS

With our extensive knowledge of cGMP guidelines, drug regulations from FDA, ICH, WHO, PIC, EU and all relevant industry standards we help you succeed with all audits carried out by agencies, accredited bodies or customers. We provide services to many customers to ensure ongoing regulatory compliance – for example mock-up inspections, gap analysis, audits of suppliers or training and implementation assistance. We have assisted several customers in solving inspection issues from FDA 483s or warning letters, and have a vast experience in the science and risk-based approach to quality issues, process validation and many other issues.

QUALITY BY DESIGN

Pharmaceutical manufacturing and development is entering a new paradigm. When applied correctly, it can be highly effective and increase flexibility, product quality and overall efficiency. It is part of the regulatory harmonisation between the USA, Europe, Japan and other countries. NNE has been involved in the preparation and implementation of QbD concepts and related practices for several years. We have carried out training, consulting and implementation for customers to ensure cost-effective solutions and compliance with future regulatory requirements.

FDA'S NEW PROCESS VALIDATION

The requirements for process validation are changing. FDA issued a new guideline in 2011 and the European GMP regulation for process validation is currently changing. There are many similarities between the new principles, and NNE has been part of the training and implementation of these principles for several years. New concepts for commissioning, qualification, FAT, SAT and the verification standard ASTM E2500 enable a cost-effective alternative to the conventional DQ/IQ/OQ/PQ approach. This can save you both money and time while improving quality and increasing patient safety. Our experts have helped several customers transform their traditional qualification and validation approaches to the new guidelines.

TECHNOLOGY TRANSFER

Pharmaceutical manufacturing is not possible without technology transfer, but it is still a challenge. Some manufacturing companies have limited resources for tech transfer. That is why NNE can provide you with an international, interdisciplinary team, who can cover everything from GMP compliance and regulatory demands to start-up of production, qualification of transferred process and project management.

Lacking the time or knowledge to implement new practices?

Get on track with future-proof solutions

Daily operations in pharmaceutical manufacturing are demanding, so facilities rarely maintain an overview of pharmaceutical trends and technologies. When manufacturing sites have to introduce new products and technologies, local experience is often insufficient. The risk is cost overrun, delayed production and postponed product launches.

When your site needs the expertise to select and implement new technology or knowledge, NNE can help you to future-proof solutions and assist you with our broad overview on new best practice technologies and solutions. We are experienced in technology assessment, selection and implementation, and are used to working with preferred suppliers.

WHY PARTNER WITH NNE?

- We assist in selecting and implementing new technology on a global scale
- We are directly involved in defining and evaluating new standards
- We have specialists who are globally recognised in their field

SPECIALITY DRUGS AND TREATMENTS

Drug products have become more complex and specialised, and this trend will continue. Small production volumes for orphan drugs and other treatments for rare diseases are part of the future agenda. Ultimately, personalised drugs and treatments in very small volumes will be hitting the market. These new treatments, diagnostics and combinational medicines are bringing new manufacturing challenges, which require both flexible and robust solutions. NNE can help you with these future-proof solutions and has already been involved in projects concerning new facilities for advanced therapies and smaller batches.

SINGLE-USE TECHNOLOGY

The demand for flexibility in biopharmaceutical has increased over the last 10 years. Combined with the right knowledge, flexible single-use equipment is a good solution to the pharma world's rapid process and technology development. The advantages are clear: lower investments, increased flexibility, faster scalability and tech transfer, and lower contamination risk. With our project experience and strong supplier relations within single-use technology we can help you find the balance between single-use and stainless steel solutions based on best practice experience.

CONTINUOUS MANUFACTURING

One of the new topics in focus in pharmaceutical manufacturing is continuous manufacturing, but very few pharma companies have tried it on a commercial scale. This type of manufacturing, however, clearly shows a level of manufacturing flexibility that no other technology can provide. There have been regulatory challenges to the adoption of continuous manufacturing, but also some very successful implementations, which have been approved. NNE has already worked with this technology and can help you implement it. Our technology experts have in-depth knowledge including the know-how to leverage the pportunities the technology offers.

NNE is an international company specialised in pharma engineering. We help pharmaceutical companies bring products to market by providing flexible, compliant and future-proof solutions.

We have close to 2,000 professionals delivering global knowledge and best practices, all dedicated to supporting our customers globally and on local sites. Through focused pharma engineering we enable our customers to deliver on demand.

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