Oral solid dosage – surviving in a new reality

FEBRUARY 2017
The world of pharmaceutical manufacturing is changing dramatically

Increased demand and competition for oral solid dosage products force manufacturers to optimise productivity and cost-effectiveness. Fierce competition is driven by a dramatic production increase, particularly in Asia, and by the general trend toward where manufacturers increase production capacity, taking over legacy products. New specialised drugs are introduced to the market, including high potency products, which put forward new and sophisticated production requirements.

More products equals new facility requirements

In 2014, the FDA approved 41 novel drugs and biologics (including large as well as small molecules), which is the highest number in 18 years and a 52% increase from the 27 approved in 2013. In 2015, 45 drugs were approved, i.e. an additional 10% increase compared to 2014. EMA recommended 82 new products in 2014 (generics included) – compared to 79 in 2013 and 57 the year before. In 2015, EMA recommended 93 medicines for marketing authorisation. This is more than 20% of all medicines for marketing authorisation. This guideline ensures that we can help out customer build e.g. a facility in Asia with the same standard and level of expertise as in Europe. Project participants can call on expertise from various experts, specialists and SMEs from all over the world. If required, engineers in Asia can support projects in US or Europe and vice versa. This might be relevant if a ramp-up of resources is required but not possible to get locally. This way of working enables 24 hour engineering. All participants have the same access to the same documents to work with and use the same approach and methodology.

This OSD design guide is based on a model facility, which is also an “off-the-shelf” offer for customers requiring a standard OSD operation established very fast. EMA has designed this facility to be compliant with current cGMP regulation related to FDA, EMA, ICH and CTD guidelines. This guideline ensures that we can help out customers build e.g. a facility in Asia with the same standard and level of expertise as in Europe. Project participants can call on expertise from various experts, specialists and SMEs from all over the world. If required, engineers in Asia can support projects in US or Europe and vice versa. This might be relevant if a ramp-up of resources is required but not possible to get locally. This way of working enables 24 hour engineering. All participants have the same access to the same documents to work with and use the same approach and methodology.

1) Lab to pilot scale and on to launch and large commercial scale production in order to keep an acceptable efficiency.

With the advance of new, more specialised products and an increase in the number of APIs that are highly potent (e.g. highly active pharmaceutical ingredients or HAPIs), comes a need for high- containment facilities, which can help to avoid cross contamination and ensure protection of operators and environment when HAPIs are used. The new trend toward high containment facilities is small-scale continuous manufacturing (or semi-continuous). Continuous manufacturing requires less space and supports efficiency and low cost of goods. Continuous manufacturing also enables a producer of highly potent drugs to manufacture these drugs in a safe way by eliminating manual transfer steps (bin to bin). During the continuous manufacturing, the product is permanently under surveillance by process analysers to ensure a high level of process control.

FDA and EU GMP promotes continuous manufacturing

Efficient technology transfer is becoming more and more important as the number of new products increases. These include transfers from:

1) Lab to pilot scale and on to launch and large commercial scale production in order to keep an acceptable efficiency.

2) One large scale production plant to another

3) Launch scale to low cost regions

With this in mind, NNE has developed an OSD design guide that enables all engineers participating in projects worldwide to work at the same high level to master projects across borders. The guideline ensures that we can help out customers build e.g. a facility in Asia with the same standard and level of expertise as in Europe. Project participants can call on expertise from various experts, specialists and SMEs from all over the world. If required, engineers in Asia can support projects in US or Europe and vice versa. This might be relevant if a ramp-up of resources is required but not possible to get locally. This way of working enables 24 hour engineering. All participants have the same access to the same documents to work with and use the same approach and methodology.

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A new playing field

Oral Solid Dosage (OSD) manufacturers are facing pressure on all sides to make production more cost-effective. New high-potency drugs are launched every year, with innovative delivery platforms such as sustained release, sprays and chewing gum entering the market. At the same time, generic manufacturers are increasing production capacity, while there is a general shift to produce in emerging markets. Moreover, regulatory requirements and health, safety and environmental standards continue to grow.

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Quality by Design – understand and control your process better

QbD products, e.g. tablets and capsules, range from relatively simple immediate release to formulations for which the release of the API has been modified to match a predefined target profile. In all cases, a robust formulation is best achieved by applying a Quality by Design methodology, which in its essence combines science- and risk-based approaches with a set of useful tools for efficient process development. Design of Experiments (DoE), multivariate modelling, mecha- nistic modelling and process analytical technologies (PAT). The collective use of these tools is key in establishing the relationship between attributes of the active ingredient, excipient function- ality, processing environment and the final drug product.

A systematic, science- and risk-based approach As a first step, the product’s overall quality parameters are defined in the quality target product profile (QTPP). These parameters can, e.g. dosage form, dosage strength and release characteristics. In the next step, a cross-disciplinary team of experts identify CQAs, critical process attributes that affect the quality of the product to the patient, CPPs (critical process param- eters), CQAs (critical quality attributes) and influencing factors related to the raw materials (excipient-CQAs) and processing technology (critical process parameters). The excipient-CQAs and CPPs are then ranked by criticality using quality risk management tools such as cause-effect diagrams (traffic light), Ishikawa diagrams, process hazard analysis (PHA), and failure mode effect analysis (FMEA). Risk assessment is an iterative process, initially relying on prior knowledge* and then updated on a regular basis as new process knowledge is gained during develop- ment and later tech transfer. Process indicators (PIs) are also important to consider as they reveal the current state of the process in real-time using instrumentation often already installed in the process equipment. Through underlying mathematical models the PIs can suggest how to adjust the CPPs. If relevant, the attributes of the raw materials, for the process to remain in a state of control (i.e. CPPs within acceptance criteria). Following the first sets of appropriately designed experimental campaigns, the design space or the multivariate-based ranges for the CPPs and/or material attributes are specified and from here the first control strategy is determined. The first control strategy is usually restricted to lab and pilot scale and needs updating for tech transfer to commercial scale and local site conditions. The control strategies are essential outcomes of QbD, as they define if relevant parameters are varied or fixed, in order to ensure that product quality (CQAs) is within specifications.

The QbD approach is encouraged by health authorities to ensure that processes remain in control, thereby minimising the risk of drug shortag- es and the impact it could have on patients.


The control strategy effectively handles known variability in the raw materials thus ensuring robust processes and a consistent product. And control your process better. Quality by Design – understand and control your process better.

What to monitor and how to act? Steering a process effectively, requires insight on: 1) which process indicators (PI) can be mon- itored in-line that predicts final product quality attributes (CQA) and 2) What to do when PIs are not where they should be – i.e. how to adjust critical process parameters (CPPs). During process development you need to identify PIs and estab- lish relationships between CQA and PI and between PI and CPP in order to make a control strategy.
Continuous manufacturing

Continuous processing can be the solution for new products. It brings benefits in production stability as well as in product control. Continuous processing is a perfect fit for small and medium-size output products. Continuous processing also supports processes that require containment. As the process is closed from start of batch with automated weighing until the final tablet is isolated, no open or manual product transfer to other containers and units is required. Batch systems are usually much bigger and require more process rooms or square meters. The approximate room ratio is 1:4 m² for continuous, it reduces the GMP footprint as well as the space for technical areas.

Batch production is typically suitable for large volume mono-productions or lines. In contrast, continuous manufacturing is 1:4 m² and the approx. room ratio requires more process rooms or square meters, which means the facility stands on is small and restricted. Then a vertical flow can be an advantage. NNE has an extensive track on different types of facilities tailored to the needs of customers and in compliance with cGMP, EHS, and all regulatory bodies. These facilities are built in Europe, Asia, North and South America.

The continuous line shown here enable the continuous manufacturing of a product from weighing of raw material to the finished tablet or capsule. In this setup, with the diversion of product to tablet press or capsule machine, you can produce either tablets or capsules. Due to the continuous process, you cannot produce both formulations at the same time. For traditional batch manufacturing, we chose a spine concept. The advantages of this include easy access and easy extension to either the right or left side of the building. Additionally, we went with a second barrier concept to avoid cross contamination and increase the safety to APIs and product migrating through the building. The space for the PAL/MAF (personal/material air lock) setup here can be built either as a sink or a bubble and is not considered as a GMP step change but as a secondary process safety barrier.

Real time release testing

Once you have developed your process using a QBD approach and have a clear understanding of material, COAs, CPPs and process indicators (Pi) and you have optimised your process using a consistent product COQs, it is possible to replace conventional end point testing by real time release testing (RTRT). At NNE, we have experience in establishing real-time end point determination of e.g. blending, granulation or drying processes in the production line. Using the process knowledge, you can control the CPPs and in-process material COQs to ensure the process is running as intended and pass control indicators (Pi) or more advanced process analysers and control loops. One example is blending. The process is controlled by NNE and is automated to stop once blending has reached its endpoint rather than after a certain time. Thereby you ensure blend homogeneity, which is often very critical for both assay and content uniformity (CU) and uniformity of dosage units (UDU).

Disolution is another example of where heavy, time consuming QC test can be replaced by a mathematical formula and calculated even before the tablet is isolated. NNE uses this technology and has a track record of supporting customers with this technology worldwide as well as supporting the equipment suppliers in further equipment development. This knowledge also enables us to provide our customers with extensive, reliable support when executing a project that involves continuous manufacturing lines.

To support you from the development of new formulations or technology, as well as feasibility study to handover of a turnkey solution in continuous manufacturing. Continuous systems are very compact, bring a high product reproducibility, demand less space compared to batch operations and they require less support equipment, less intermediate handling and immediate storage in between process steps.

Faster to market with continuous manufacturing development

Data shows that new products developed using continuous manufacturing are “faster and cheaper to market” and consume less API for development (typically only 10% compared to a batch trial setup). Continuous manufacturing is probably the next major step in OSD manufacturing. The advantages listed below have driven several “big pharma” companies to invest in continuous processing:

- Fully closed process
- Small GMP footprint
- Reduced intermediate storage space and low inventory
- High automation level based on PAT and process modelling
- Lower development costs (reduction of historical data makes the foundation for new product development)
- Reduced scale up between labs, development and production scales
- Flexibility in production/size (by adjustment of manufacturing time)
- Consistent and high quality of drug products
- Increased process control with PAT (process analytical technology) is key when implementing continuous manufacturing

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- Small GMP footprint
- Reduced intermediate storage space and low inventory
- High automation level based on PAT and process modelling
- Low variability of products high yield and low capital cost
- Faster time to market
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Continuous Manufacturing line CONSIGMA from GEA (from weighing via, granulation, drying, sieving, blending, tablet compression)

FACILITY LAYOUTS

Depending on the type of production (single-product production, batch production, continuous production) there are different layout scenarios. A layout usually reflects the demand of the facility with a 100% load in the future. Additionally, a layout design takes into account possible future expansion. These expansion possibilities can be foreseen at an early stage of planning. It can therefore be essential to determine the production strategy of a facility. The production strategy — is it batch or continuous — is for example vertical process flow or horizontal process flow. Sometimes horizontal flow is more compact and reduces your GMP footprint, but choosing the right process equipment. Explantability can be an interesting challenge if the ground the facility stands on is small and restricted. Then a vertical flow can be an advantage. NNE has an extensive track record of different types of facilities tailored to the needs of customers and in compliance with cGMP, EHS, and all regulatory bodies. These facilities are built in Europe, Asia, North and South America.

Modular engineering equals fast-track projects, easy reuse and high flexibility

Establishing the right capacity in the right time is crucial, and one way to achieve this is to use modular design. Flexible facility design has been broken down into logical modules. This enables to adapt the functionalities, giving the project additional flexibility and making project changes more feasible.

Suppliers

NNE has a close relationship with many of the suppliers of OSD process and fill equipment. These relationships make it straightforward to deliver the right equipment. During projects, these suppliers work hand in hand with our process and building engineers to deliver a successful project on both sides. NNE has executed projects that contained almost all existing OSD processes (storage, raw material check, powderers/driers, banding, dispensing, shifting, milling, drying and wet granulation in either high shear or low shear fluid bed, extrusion, drying, coating, blending, direct compression, roller compression or compression tableting and packaging).

In the past years NNE has made projects together with the top tier suppliers of e.g. DEA, Glatt, Bosch, Anhydro/SPX, Fette, Korsch, GEA Courtoy, Waldner, DEC, Amixon and Lodige on almost all continents.

Standard OSD facility

NNE has developed a standard OSD facility design for a multi-purpose facility on the back of many years of experience building OSD facilities worldwide. The OSD design guidelines support fast engineering approach and provides a standardised design document to design OSD facilities for NNE affiliates all over the world. Every project participant uses the same approach and design documents.

One major choice needs to be made before executing a design; do you want horizontal flow or vertical flow? The standard OSD Facility shown here is based on a horizontal flow in spine concept (see layout multi-purpose batch manufacturing facility). This design comprises the possibility of producing multiple products in a safe way compliant to all authority requirement. The design facilitates the possibility to upgrade later to use potent APIs by using a second barrier concept, hence the PAL/MAL to minimise potential cross-contamination. This design enables a flexible process setup – also in the possible future extension.
Maintaining high quality in the completion of a high potent OSD

Customer
Roch Shanghai, China

Facility/area
The facility boasts 2,500 m² production area distributed on 2 levels.

Challenge
Time pressure and a tight deadline

Solution
Agile and flexible engineering

Project duration
August 2012 – 2015

Services provided
Pre-concept design, conceptual design, basic design and EMCMQ (engineering, procurement, construction management and qualification).

NNE and ISPE containment workshop

NNE is active participating in major pharma-aceutical associations and authority panels. We are first on line when new drafts, handbooks and guidelines are presented.

So when ISPE Affiliate Germany, Switzerland and Austria held a containment workshop in Bad Dürkheim, Germany and the new ISPE Containment Handbook was released NNE was present. Only a few weeks after its release, it was clear that the industry con-sider this book as a guideline and as a new standard to be applied.

Containment HAPI

Handling highly potent active pharmaceutical ingre-dients (HAPIs) in oral solid dosage (OSD) production accelerates the need to upgrade existing facilities or build new ones.

OSD API PRODUCTION SERVICES

- Highly potent API containment strategies
- HAP risk assessment
- Definitions of information about hazardous and other pharmaceutical processes
- Necessary containment equipment solutions

Safety and regulatory compliance are key factors when dealing with highly potent APIs used for e.g. oncological dosage forms. The main challenge lies in protecting the production staff and the environment while also protecting the product from contamination and complying with local regulations.

NNE engineers provide expertise within GMP requirements and highly potent technology. We help you to design and construct facilities that produce highly potent OSD APIs in a safe and contained manner that complies with all local and international regulation and requirements.

NNE has built multiple facilities in the past years that involve handling of potent material down to less than 30 ng/m³ (OEB5) and has been involved in upgrades to bring existing facilities to a state-of-the-art level to ensure safe operators and avoid contamination and migration of highly potent API in a facility. Measures for required operator protection mainly depend on:

- The danger of the product (OEL)
- The physical characteristics of the product (liquid, powder, tablet, etc.)
- The type of process (disperse or not)
- The amount of product handled

Handling highly potent APIs in oral solid dosage production involves a high level of compliance and commitment to safety.

NNE, the global specialist in biopharma, is dedicated to creating safe facilities for the pharmaceutical and biotechnology industries.

CHEMICAL INHALATION RISK ASSESSMENT FOR HIGH POTENT PRODUCT

NNE has developed a tool to make a chemical risk assessment for high potent products. The tool enables to quickly make an inhalation risk assessment at different process steps where highly potent chemicals are used. It is part of an initial health, safety and environment (HSE) evaluation if potent ingredients have been identified. This tool has a background in a chemical database that contains a collection of various potent APIs including their properties according to their material safety data sheets (MSDS).

With the output of this tool, NNE can engineer the right solution to each process according to the occupational exposure limit (OEL) requirements.

OEL OCCUPATIONAL EXPOSURE LIMIT
CAT: CATEGORY ACCORDING TO ISPE

G 4 (5)
Very high pharmacological and toxic effect

G 3a (3)
High pharmacological and toxic effect

G 2 (2)
Medium pharmacological and toxic effect

G 1 / 1
Low pharmacological and toxic effect

Risk assessment if an isolator is necessary for open handling

Risk assessment if an isolator is necessary for open handling

CAT / (OEB)

G 3b (4)

G 1 / 1

OEL

Effect

CAT / (OEB)

OEL

Effect

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The goal of technology transfer activities is to transfer product and process knowledge between development and manufacturing, and within or between manufacturing sites to achieve product realization. This knowledge forms the basis for the manufacturing process, control strategy, process validation approach and ongoing continual improvement.”

NEW APPROACH TO PROCESS VALIDATION
Process validation is not only a regulatory requirement, but also very good business. If you understand the process you can predict the outcome and ease optimisation of the process and product. Of course it also proves that the process is safe and effective. Process validation is about collecting and evaluating data from the process design stage through commercial production. The data establishes scientific evidence that a process is capable of consistently delivering quality meeting predefined specification and quality attributes. Process validation of a product lifecycle must be established in three stages as illustrated in figure 1.


In order to consistently deliver quality products, it is equally important to ensure the safety and efficacy of your products, quality must be built in and maintained throughout the manufacturing process at every step right from the beginning. This can only be done if process understanding is present. Process understanding is essential in supporting qualification and process validation activities. Process understanding and proof of mitigation effectiveness can be achieved by applying Six Sigma tools such as Gage R&R and critical process parameter (CPP) for legacy products. Identification of a control strategy (simple or advanced) must be performed and the data obtained must be trended using statistical tools.

The question is where to start with legacy products? A good starting point is to make a priority list of all your legacy products, including justification of the priority.

FUTURE REQUIREMENTS - QUALITY NITECS
FDA’s new quality metrics programme is supposed to be a tool to help planing GMP Inspections.

• The objective is to measure the quality of a processes or products.
• Quality is the fitness for intended use of the product, relevant to patients and quality. It is a measure of a site’s ability to manufacture products fit for intended use. It is also an objective measure of the effectiveness including the pharmaceutical quality system.

TYPICAL CHALLENGES
• To learn about the new approach
• To understand the risk assessment
• To learn how the new approach impacts development projects and legacy products.

How can NNE help?
• With a training programme adjusted to your specific situation

1. Process design
2. Process validation
3. Ongoing/continued process verification

With a workshop which will kick off and deliver a process validation strategy, plan and identified list of deliverables.

With training and/or execution of risk assessment, statistics such as DoE and “stage 1” monitoring program.

With training and education in process validation in general (e.g. ICA, IPE, FDA).

In the attempt to continuously discover new products as well as next generation products, the industry is developing new product candidates at an accelerated rate. In 2014, the FDA approved 41 novel drugs and biologics (including large as well as small molecules), which is the highest number in 18 years and a 52% increase from the 27 approved in 2013. In 2013, 45 drugs were approved, i.e. an additional 10% increase compared to 2014. EMA recommended 82 new products in 2014 (generic included) – compared to 79 in 2013 and 57 the year before. In 2015, EMA recommended 93 medicines for marketing authorisation. This includes recommendations for 39 new active substances. More than 90% of these applications are forecast to be treatments for rare diseases.

The technology required for local manufacturing is likely to become available in different markets in the near future due to patent expiry. Demographics and local market forces in emerging markets such as the public-private partnership models drive the business of promoting access to these products. This places emerging markets in a position to lead the way in the innovation of flexible, multipurpose and cost-effective manufacturing.

The technology required for local manufacturing is often sourced from established technology providers that already have ongoing programmes for developing and updating products. Ensuring successful technology transfer from these technology partners is crucial for a fast establishment of local pharmaceutical manufacturing.

Pharmaceutical products can be highly complex and the notion that “the product is the process and the process is the product” is widely acknowledged by the regulatory bodies. This underlines the importance of product and process knowledge and project execution to support successful technology transfer and market entry on time.

NNE was born and raised with the process and market forces in mind from the beginning. NNE represents the major growth engine of the global pharmaceutical industry with a high unmet demand and very little local manufacturing. To unlock this huge potential, you’ll have to look at the enablers and critical points in technology transfer.
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.

NNE.com

Global reach – local knowledge

Our oral solid dosage experts

Jacqueline Vu
Global Technology Partner

Jacqueline Vu has worked in international pharmaceutical engineering for more than 20 years. She has broad experience of working with feasibility and front-end studies as well as with conceptual design, detailed design, logistics and selection of material handling equipment and assistance to construction.

Jacqueline possesses extensive oral solid dosage (OSD) project experience with a particular focus on automated OSD plants (automating material handling systems, gravity flow, closed systems and OEE improvement).

Sven Oliver Gottlieb
Principal Consultant

Oliver has worked with oral solid dosage (OSD) for more than 13 years. This includes project management, engineering and operational tasks within a pharmaceutical engineering company and a pharmaceutical company.

Oliver possesses extensive OSD project experience and has worked with feasibility and front-end studies as well as with conceptual design, detailed design to construction, troubleshooting and de-bottlenecking. He currently works in the process technology consulting group and offers consultancy services pertaining to OSD and containment. He is responsible for establishing the global OSD design guide that sets the global NNE standard for OSD facility design.

Morten Allesø
Senior Consultant, PhD

Morten has 7 years of experience in the pharmaceuticals industry and is a dedicated, results-driven oral solid dosage (OSD) expert with a Master’s degree in pharmaceutical sciences and a PhD in process analytical technology (PAT) for pharmaceutical applications.

Morten has practical experience of implementing Quality-by-Design (QbD) methodology in the development of new solid dose form products in order to improve effectiveness (“right the first time”) and efficiency (e.g. reducing time spent on early formulation development) and also in troubleshooting and improving performance of commercial tablet production.

Line Lundsberg-Nielsen
Global Technology Partner

Line Lundsberg-Nielsen is a physicist and has worked in the pharmaceutical industry for 20 years. She has a wide experience from both R&D and Manufacturing been working with science and risk based approaches such as Quality by Design, Process Analytical Technology and Process Validation.

Line has practical experience from developing, implementing and getting regulatory approval of a control strategy for an OSD based on PAT including NIR and with full Real Time Release Testing of the product. She is familiar with the regulatory processes used for CMC approval in both FDA and EMA and for lifecycle maintenance.