# COMPETENCE CENTER

Test, develop and optimise. That's what we do together.





### IMA ACTIVE COMPETENCE CENTER

THE PHARMACEUTICAL MANUFACTURING PROCESS HAS PRECISE REQUIREMENTS AND GUIDELINES FOR PRODUCT QUALITY.

leverages the know-how and experience gained over the past five decades to help pharma companies accelerate the R&D development process, optimise and customise production processes and conduct trials in an innovative way. As a specialised unit devoted to fostering and developing expertise in Oral Solid Dose, the IMA Active Competence

The IMA Active Competence Center Center serves as a centralised hub for knowledge and resources, providing support, training and guidance to individuals or teams working within that domain. The IMA Active Competence Center collaborates closely with all IMA Active technical departments to drive innovation, improve processes and maintain a competitive edge in OSD innovation.

# TEST

Wherever you are and whenever you require support or supervision from our OSD processing experts, the IMA Active Competence Center team is ready to partner you during all the production phases, from process implementation up to process validation. Our first-hand experience within the industry will facilitate each step, enabling customers to optimise their investment by outlining the context, identifying key parameters and securing the ideal approach from an early stage.







### PROCESS IMPLEMENTATION

The IMA Active team is able to guide the customer at all stages of production (handling, granulation, tableting, capsule filling and banding, weight checking, coating and washing). Our experts can be present globally to support customers whenever a process supervisor is needed.



### PRE-REGISTRATION SUPPORT

During product registration, the customer receives support to identify and test process limits and ranges. IMA Active can also help customers to run technical and preliminary tests in preparation for a successful process qualification phase.



### FEASIBILITY STUDY

Performing a comprehensive analysis with the customer helps evaluate the feasibility and potential success of a proposed project or process. This investigation is fundamental in order to determine whether the project is achievable and worthwhile.



### **PROCESS RISK ANALYSIS**

According to the process risk analysis method, the IMA Active team analyses, identifies, assesses and mitigates the potential risks associated with the various pharmaceutical process stages. This analysis results in the design of a safe production process where potential hazards are minimised and production resilience is enhanced.



### PROCESS VALIDATION

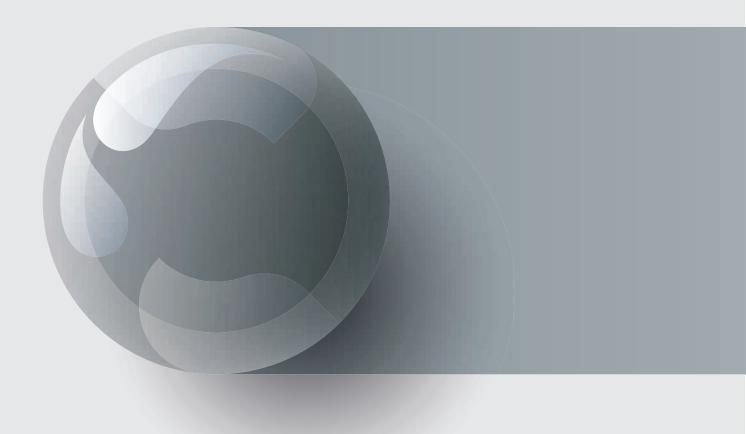
Thanks to a systematic approach, the consistency of a production process can be validated. The IMA Active team documents and checks if the process fulfils predetermined quality standards and specifications, meets regulatory requirements, and reliably manufactures safe and effective products.





## DEVELOP

We take every opportunity to proactively guide you throughout key phases such as formulation development or when technical batches will tune the process for qualification and validation. By transferring vital know-how and suggesting correct methods for important tasks, we follow your team closely as they approach machine start-up time. The IMA Active Competence Center contains a wealth of knowledge that customers can tap into to make sure their objectives are achieved.









### FORMULATION DEVELOPMENT SUPPORT

IMA Active qualified technologists and specialised engineers work closely with customers to achieve the best result for every step of formulation development. The IMA Active team helps customers to optimise existing formulations and for process scale-up or scale-down.



### UP AND DOWN-SCALING

More and more often, the team works together with the customer's experts to define the best procedure for proper up and down-scaling. IMA Active has a large database and consolidated experience that guide its specialists in this mission, choosing accurate parameter ranges and the best set-up for equipment and machines.



### **TECHNOLOGY TRANSFER**

Customers receive support to transfer knowledge, processes and expertise from R&D to manufacturing. Not only does this close cooperation support the transfer of both formulations and manufacturing protocols, but also ensures the appropriate technology is implemented for consistent and reproducible processes.



### PROCESS AND CLEANING VALIDATION

Using a QbD approach, IMA Active supports customers in improving process yields, final results and in finding both the right manufacturing and cleaning methodologies. In a systematic approach to achieve final desired product quality, the IMA Active team assists in the development and optimisation of all the critical pharmaceutical processes.



### MACHINE START-UP

After installation of IMA equipment at the customer's site, the IMA Active team will follow all the activities related to a proper installation and qualification of the machine. Once this step has been completed, together with the customer's experts, technical batches will be launched to sharpen the process and obtain process qualification and validation.





# OPTIMISE

Whether you are initiating a new production process or adapting an existing one to the market's evolving needs, the IMA Active Competence Center is at your disposal to optimise every aspect that will impact your product, your facility and your performance. Training opportunities, remote assistance, troubleshooting and a broad selection of educational topics are available and can be tailored to expand your knowledge and skills. Our aim is to provide you with the tools to optimise your production.









### ONSITE PRODUCT AND PROCESS OPTIMISATION

After acquiring preliminary knowledge of the customer's product and process in the laboratory, the IMA Active team can be present at the customer's premises to cooperate together in starting a new production, optimise an existing process, run technical batches and supervise process characterisation and validation.



### TROUBLESHOOTING

The IMA Active team offers direct production support at key stages, such as initial start-up after installation or during production flow. Specifically, the team takes care of troubleshooting for formulation definition, product and process development to understand the root causes of each phenomenon and solve any issue by using a systematic approach.



### **REMOTE ASSISTANCE**

IMA Active technologists and process engineers are available if remote support is required. Direct contact with the customer enables IMA Active experts to prove support for process implementation and recipe adjustments. Remote support guarantees efficient communication, rapid response times and economic savings for the customer.



### TRAINING

Expertise is of little or no use if not properly transferred to customer: this is crucial for the achievement of high-quality standards. IMA Active organises tailor-made training sessions on all OSD production process-related topics, whether at IMA or at the customer's premises. Digital training is also available for enhancing portability and repeatability of the course.



### EDUCATIONAL PROGRAM

Customers can discover more about IMA Active processes and technologies through specific webinars, scientific seminars organised in collaboration with pharmaceutical partners, suppliers and Academia, as well as presentations, posters and case studies, disseminated in dedicated events.







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