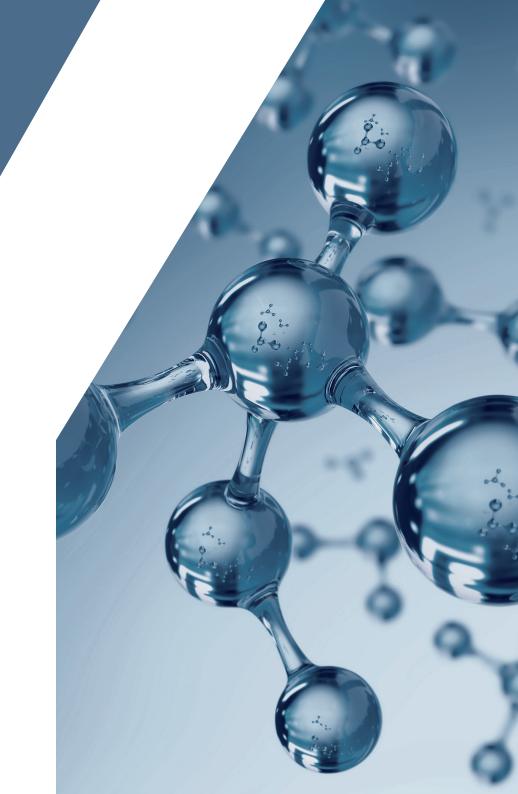
In house production of medical isotopes

Connecting the elements





In house production of medical isotopes

In healthcare, the trend is towards personalized care. Personalized care is customized to the patients and supported with technical development. An important development for personalized care in diagnostics and oncology is the ability to produce nuclear isotopes with a small cyclotron in the hospital.

Introducing the production of nuclear medicines on site requires the establishment of a radiopharmaceutical production facility. For a successful implementation, alignment between the clinical imaging department and the production facility for nuclear medicines is vital. Because of the long-life expectance of the equipment, it is important to think about future development already. New treatments and associated equipment also require structural

modifications to the existing building and facilities.

Production of nuclear medicines on site also requires the establishment of a logistic chain; raw materials, waste management, medical isotopes, hot cells, nuclear medicines and application to the patients.

"Implementing specialized equipment and modifying buildings in operation is complex and requires an integrated project management approach. Yellow project management is your partner for complex projects.

We are independent and experienced with project management in the nuclear medical industry"

Choice of treatments and accociated traces **Products** (patiënt) Implementation of production and treatment Delivers specifications for optimal performance 1 production lab 2 quality control 3 hot lab 4 maintenance **Equipement** 5 GMP requirements (supplier) 6 etc.

The integral process with the cliënt, disciplines, stakeholders and external suppliers is complex

First time right

Yellow project management delivers 'customized project management' similar to 'personalized healthcare' where the ambition and goal of the client are key.

We start with examining the ambition and goal of the client until these are fully expressed and clear.

For a hospital the implementation of a radiopharmaceutical production facility is not a common activity. The main components of a facility have an expected lifetime of about 30 years. In the field of personalized healthcare, new treatment methods are expected in the near future. When designing a new facility, it is recommended to anticipate to future pharmaceutical developments and even the final decommissioning. Subsequent modifications to the radiopharmaceutical production facility will be complex and costly.

Yellow supports the hospital with a design that takes into account space and facilities for future expansion. Based upon knowledge of current technology and with an eye to the future, we will advise whether it is possible to achieve greater flexibility for the future with limited additional investment.

Decommissioning

Decommissioning of a used facility is even harder than building a new one. Most regulatory agencies require a plan of approach with a cost estimate before issuing a permit for operation. Writing a balanced decommissioning plan reduces the necessary financial guarantee for the operational license. Yellow has practical hands-on experience with various decommissioning projects.





We support our client through the entire process. Based upon our motto "start with the end in mind" we will start with our clients to define a clear vision of their desired outcome. In this phase we challenge our clients to think as broadly as possible and use all features of the new equipment. The result is a clear, measurable, and singular interpretable specification of the project. Alignment of the defined result is key for a successful project.

With a clearly defined result, we determine the necessary steps according to our approach, **the creativity leap**: going back from the defined result to the current situation. By doing so, we reversely define the necessary process steps. The traditional approach based upon incremental steps from the current situation has the risk to encounter "forgotten" but necessary actions later on in the process.

Based upon the defined steps, the involved stakeholders are determined. Our approach is dedicated to create cooperation between all stakeholders. With all stakeholders aligned, the result will meet expectations and the purchased equipment does perform to its full potential.





Each supplier has its own set of requirements. Together with the hospital and the supplier we balance the possibilities in the given hospital layout. We combine our practical knowledge with the experience of the suppliers. This knowledge and experience are brought into the design and construction activities.

Deviations from specifications during construction can have a major impact on the productivity and usability of the facility. Correcting errors after completion takes a lot of time, money and subsequent availability. We know the critical components therefore we monitor them extra during construction. This prevents delay in the start of operation and sub optimal use of the facility over the entire lifespan.

Depending on the experience of the hospital and the complexity of the project, we can support the purchasing department in tenders to purchase the equipment. We challenge the vendors to deliver the most added value instead of the lowest bid.

Yellow project management is your independent partner to establish a well designed and built radiopharmaceutical production facility.



Design and verification

for managing our work and to make sure all requirements are met at the end of the project. The V-model is often used in the GMP (Good Manufacturing Practice) guideline as a model for system design. We apply the corresponding stages and validation steps in our project management approach.

Defined result

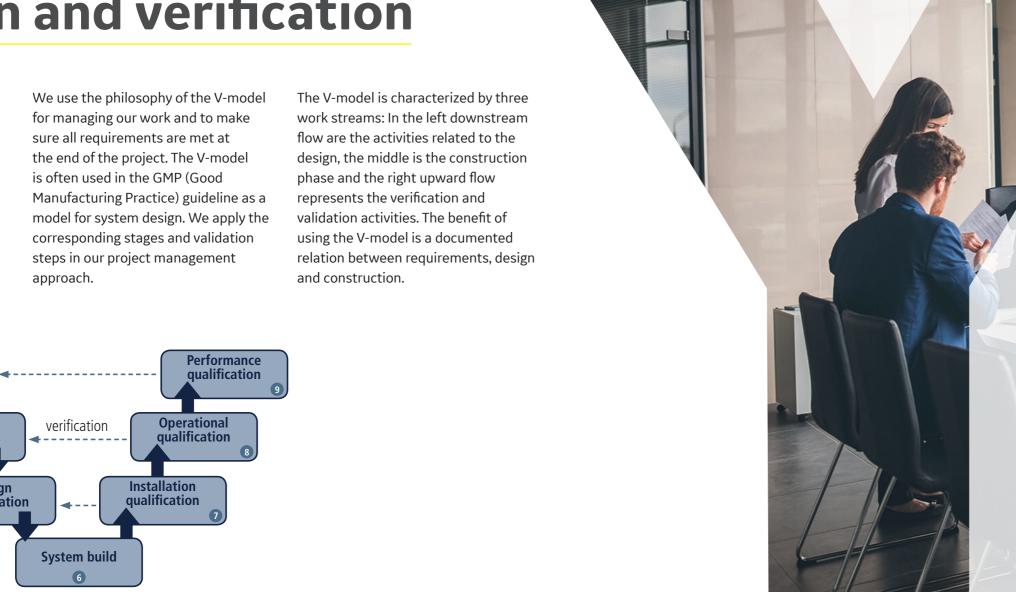
Plan of Approach

User requirements

Functiona

requirements

Design specification



ELLOW Project management

Success starts with the end in mind

We help our clients by clearly defining the desired outcome of their project. We do this based upon our philosophy of the creativity leap, supported by proven tools for project management, contract management, construction management and risk assignments.

Yellow project management is an independent project management company. We are specialized in project management for nuclear construction related projects. Our strength is to turn ambition into plans and reality.

Consultancy

- Construction related project management and technical advice
- Purchasing strategy
- Second opinions
- Dispute resolution

Nuclear medicine

- Project and construction management
- · Design of laboratory and irradiation facilities
- Setup functional & technical requirements
- Waste strategy and handling
- Site management

Decommissioning

- · Project management
- Site management
- Plan of approach
- Time schedule
- Cost estimate

