Re-engineering the design process for the pharma industry

A review of how one company devised and implemented a new business process to provide a low-cost, high-quality engineering service - from plant design through to validation.

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Today, R&D-based pharmaceutical companies are responding to tougher market conditions in a number of ways in their efforts to remain competitive. These include undertaking mergers and acquisitions, focusing on the core businesses of R&D and marketing, delaying decision-making for new capital investments, achieving a reduced time to market for new products, and building new facilities in tax havens.

Kvaerner has responded by developing a three-pronged, new business process. First, by using technical consultants who work with business and technical staff, the company aims to ensure that the concept of every endeavour is fully tested and proven to be founded on a sound basis. Second, low-cost but high-value design centres and IT systems are used to engineer, procure and construct the resulting plant quickly and cost-effectively. Third, a streamlined validation process is used to get the plant into beneficial production as soon as possible. The overall intention is to avoid sacrificing quality, whilst minimising the cost of the engineering service and the time to beneficial production.

Critical investments that maximise returns

There seems to be no end to the constant round of mergers and takeovers in the pharmaceutical industry. This, combined with a focus on core businesses and delayed decision-making for new investments, has resulted in a need for strategic analysis of the supply chain and in-depth studies of all proposed developments. Pharmaceutical companies seek expert advice on their investment plans in a wide variety of ways.

Responding to this, Kvaerner’s Process Business has employed consultants in a range of disciplines; each is an expert in his/her respective field, including experience with a pharmaceutical company in a manufacturing or engineering capacity. Examples include:

- Architects and HVAC specialists who can apply the best practices in GMP, containment, materials and personnel movement,
- Automation consultants who appreciate the trend towards Manufacturing Execution Systems and can set out the overall strategy for plant management information,
• Secondary equipment specialists with an industry-wide knowledge, who can readily narrow down the choices available to optimise the requirements,

• API and containment consultants who work with the latest, most toxic products and processes,

• Environmental control experts with experience in containment and climate control,

• Biopharmaceuticals specialists who are at the forefront of developments in technology,

• Strategic analysts who can assist with supply chain optimisation, product pack rationalisation and technology transfer, and

• cGMP compliance specialists who carry out on-site training, and can streamline clients' engineering and validation documentation and procedures.

A small team from the consultants’ group is formed for each concept study; this is typically carried out at the client’s site where the key business and technical managers are located.

**Engineering, procurement, construction and validation (EPCV)**

Once a design has been optimised and successfully gone through the rigours of budget approvals, it is imperative that the engineering design and procurement phase is undertaken at a low cost and with a programme which is as short as possible, without becoming “fast track”.

Simple cost reduction without regard for quality and schedule can be readily achieved but would, of course, be an unsatisfactory solution. Kvaerner’s strategy is to employ low-cost centres that participate in the engineering phase within a quality-controlled environment.

Attempting to lower the costs of engineering within Europe achieves little, since the engineering contracting industry is very mature and has honed its processes to a very fine degree. Most attempts to reduce design costs result in lower quality and increased time-scales as a result of adopting short-sighted measures.

Global distribution of an organisation’s operations can be a strength, but can also represent a huge challenge to maximise effectively. It was to address this challenge that Kvaerner developed a strategy to disperse engineering and procurement work. The strategy envisaged developing and implementing computer systems that would enable any operation to work with one or more operations in any part of the world - that is, not simply to work together but to work with systems that:

• Integrated the design process from the conceptual stage through detailed design, procurement, construction and validation,

• Resulted in correct, complete and consistent data throughout - in other words, high quality data management and control, and

• Provided the plant operation with a wealthy data bank for the ongoing maintenance, development and production control of the plant.

Figure 1. The conceptual design process. The hub represents whichever systems are employed, and each participant shares access throughout the entire life of the project, using their own chosen systems but sharing the results via the Docbase over the web.

Figure 2. The interactions between Kvaerner systems and those of its vendors or associated contractors. Documents are placed into the project Docbase and are accessible to everyone who needs them.

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This strategy resulted in the development of systems that are now independently marketed as the leading integrated tools for the industry. The level of commitment to this strategy ensured that every Kvaerner design location adopted the tools, invested in the infrastructure and training required, and became a part of a global design community. This strategy came to fruition just in time, enabling the company to offer its pharmaceutical clients the benefit of high-value, low-cost engineering undertaken in one of several Asian operations, whilst maintaining project management and control from one of its pharmaceutical centres, such as the UK Solent operation.

Information systems strategy

Consultants require a wide range of computer systems that they can use as their tool-set; their place of work varies and typically can be a client’s premises, a hotel room, their own home, an airport or back in the home office. In these situations, the best that they can expect from a network is to connect via a telephone line; this points to a Web-enabled solution rather than the more capable but demanding Client-Server approach.

The volume of information generated at this stage of a proposed plant is never vast, and integrating the information with “downstream” systems is really a low priority. It is, however, vital that a consultant is aided by the systems and can develop his/her full creativity unhindered. An example of this can be seen in a recent architectural design where the architect hand-drew the overall concept in a series of sketches, and then - using scanning and advanced graphic packages - stored, adapted and distributed the resulting proposed design to obtain the planning authority approvals.

One essential ingredient of the conceptual tool-set is a common document repository that can be accessed by anyone with a part to play in the project - be they the client, approval authorities, sub-contractors or vendors. The system uses Documentum EDM, accessible via the World Wide Web using a fully secure Extranet and web-enabling tools.

This document repository - the “Docbase” - is the start of the collection of deliverables that will one day be handed over, and forms a key part of the plant information system. It also serves as an information resource that consultants can use to leverage their designs, using parts of previous designs. The system is operated as part of an electronic workflow process where versions of documents are controlled, checking and approval of designs takes place, and those participating are automatically notified of events occurring in the Docbase. Such notifications occur through e-mail.

Every conceptual design represents an occasion when numerous very busy personnel from the pharmaceutical company, the consultants and some external specialists from vendors or government authorities must collaborate, make decisions and get agreement on the final concept. Using the Extranet and the Internet, along with specific workshops, Kvaerner has completed many successful concept studies with complete “team buy-in”.

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Figure 3. The process by which every document produced during design or by vendors or design subcontractors is stored, retained and controlled in the electronic document vault; this vast repository is routinely handed over to the client's operational team.

Figure 4. An illustration of how Kvaerner is proceeding to engineer, procure and construct a European pharmaceutical project - a new Irish facility near Dublin for Bristol-Myers Squibb.

This whole process is illustrated in Figure 1, where the hub represents whichever detailed systems are employed - including the Docbase to store the deliverables - and each participant shares access...
throughout the entire life of the project. The system extends to estimators, project planners and cost controllers, as well as the direct technical specialists. Each uses their own chosen systems but shares the results via the Docbase over the web.

**Low-cost, high-value engineering centres**

Once the early plant design has crystallised and the sanction to continue the venture has finally been achieved, the focus turns to detailed engineering, procurement and construction. Of these different phases, construction has to be the main driver and, in turn, this will only be successful if:

- The designs are delivered in the correct phasing to enable construction to flow smoothly,
- Equipment deliveries are made on time,
- All bulk materials are provided to site when needed and fully controlled once there,
- The design is properly integrated so that construction proceeds smoothly, without clashes necessitating costly dismantling and re-builds, and
- The construction contractors have a comprehensive set of design instructions in the form of documented information, databases and 3-D models.

Kvaerner systems start the process of integrating the design information from the beginning of the production of intelligent P&IDs (piping and instrumentation diagrams). The data from these flows into a Project Engineering Database, and is shared and developed by process, mechanical, piping, instrument, control and electrical engineers and designers. The resulting deliverables from this system include all of the non-spatial design documents such as datasheets, equipment lists, instrument indices, load schedules and line lists. The database system employs advanced referential integrity to ensure the elimination of errors, a flexible checking and approval system controlling data, and version control of all data with instantaneous change highlighting.

The partner to this data-management system is the 3-D modelling system used on almost every plant design. This is far more than a visualisation of the design, and uses powerful databases to develop the entire spatial materials take-off of the plant, down to the smallest item that has to be procured. The system automatically tracks and announces all forms of clashes - whether between pipes and equipment, or incursions into access ways or maintenance corridors. The model is itself a deliverable to the plant site, and provides an invaluable aid to the constructors as the plant unfolds. Countless deliverables come from the model, including detailed isometrics for every pipe.

The systems do not stop at the materials

![Figure 5. A snapshot from a 3-D model of the Bristol-Myers Squibb Dublin plant, developed by Kvaerner’s Indian operation in Mumbai.](image-url)
Numerous lessons have been learnt - the most obvious being that communication is a vital part of every project, particularly when the design team is split across three continents.

Hand-over of information

The scope for hand-over of data and electronic documents is enormous. Most pharmaceutical operations require every document to be stored electronically in their own repositories, and Kvaerner is able to pass these from Documentum using its own technique that preserves the "meta" data describing the documents, as well as the documents themselves.

The process by which every document produced during design or by vendors or design sub-contractors is stored, retained and controlled in the electronic document vault is illustrated in Figure 3. This vast repository is routinely handed over to the client’s operational team. Figure 4 illustrates how Kvaerner is proceeding to engineer, procure and construct a European pharmaceutical project - a new Irish facility near Dublin for Bristol-Myers Squibb. Work is shared with the company’s Indian operation in Mumbai, which developed the 3-D model. Figure 5 is a snapshot from this model.

A minority of companies also require the data from Kvaerner’s databases and the 3-D model; this will surely be an increasing trend since the value of this information post-construction must be enormous.

Significance for future strategy

Despite the expected implementation issues, Kvaerner certainly rates the new system to be successful and the process is now a major part of the company’s strategy for delivering high “value for money” on its projects.

Numerous lessons have been learnt - the most obvious being that communication is a vital part of every project, particularly when the design team is split across three continents. Good communication of multiple changes (endemic in plant design) is difficult but essential. Computer systems, backed up by frequent video-conferences, still require teams to talk face-to-face. As a result, the company now anticipates this and routinely stations a supervisory team of engineers in its low-cost design centres; these experienced engineers ensure that communication is adequate and misunderstandings are avoided.

The company has also strengthened the communications infrastructure and has invested in a higher speed network connection to Asia, as well as deploying the latest web-enabled facilities to economise on bandwidth usage. There is no question that Kvaerner sees this way of working as a success, and one that is shared by customers, who gain a lower cost project without loss of essential quality.

David Cockshoot is a Director of Engineering and IT with Kvaerner in the UK. Within this post, he has sponsored a major Business Process Re-engineering initiative to enable the company to work collaboratively with high-value, low-cost engineering centres in India, and with design-and-build sub-contractors. He joined Kvaerner in 1974 and previously held positions in IT/CIE, with responsibility for information systems for the UK operation and the development of the ENGINES (VANTAGE) and AutoFLOW (ASPECT) engineering systems. Mr Cockshoot has 20 years’ experience in the pharmaceutical industry; he holds an engineering degree from Queen Mary College, University of London, and is a Fellow of the Institution of Electrical Engineers (IEE).

Notes: "ASPECT", "VANTAGE", "FOCUS" and "PDMS" are provided by the CADCentre plc. "PDS" is provided by Intergraph Inc. "Documentum EDM" is provided by Documentum Inc.