De Montfort University	**Challenge** Prepare the next generation of employees to support pharmaceutical companies in optimizing product quality and achieving their core missions to improve patient outcomes.

Preparing students for quality careers in pharma

De Montfort University offers students the opportunity to learn from pharmaceutical industry experts

This is the era of big data. Organizations around the world are increasingly digitizing operations and finding new ways to deepen process knowledge and control. This shift calls for a new breed of employee equipped to use data visualization and analytics to achieve desired outcomes. And Leicester, England's De Montfort University is helping fulfill demand for data-savvy graduates.

Among the university's innovative offerings is a one-year intensive pharmaceutical Quality by Design (QbD) Master of Science (MSc) program. The set of courses prepares students entering the pharmaceutical industry to support their employers in conducting more effective experimental designs and interpreting the results. A core focus of the program is the translation of raw data to useful information and insights, made possible by data visualization and analysis – and by JMP®.

Propelling students from academia to industry

One notable aspect of De Montfort's approach to teaching is a close collaboration between academia and industry. A good example is its QbD program, which can lead to certification or an MSc degree, depending on the courses completed. The university developed this program with input from pharmaceutical leaders such as Glaxo-SmithKline (GSK), Bristol-Myers Squibb, AstraZeneca and Pfizer. "The involvement of practitioners and regulators with experience at the cutting edge of the industry enables students to access the best Quality by Design practice from around the globe," says Walkiria Schlindwein, MSc program leader. "We have been working closely with industry for over seven years to develop efficient and rapid methodologies to produce high-quality medicines and innovative approaches to teaching."

"One thing that makes our Quality by Design program unique is the open collaboration across industry, academia, consultants and software vendors," says Martin Owen, a part-time De Montfort lecturer who, after a 30-year career with GSK, himself embodies the academia-industry partnership. "As a result, we can provide a hands-on, pragmatic introduction to Quality by Design, using a motivational mix of theory, case studies, simulations and practice."

In addition to teaching, Owen is also a director at Insight By Design, a consultancy that offers training and advisory services to both industry and academia. "Knowing the tools is not enough," he says. "Knowing when and how to use them is key to success." A Lean Six Sigma Black Belt, Owen spent two decades at GSK, where he played a pivotal role in implementing QbD as Manager in Pharmaceutical Development. He is also an Associate Consultant at Prism. "Quality by Design is fundamental to the design, development and supply of medicines," Owen says, "from product design to continuous verification."

From data to insights

At the heart of QbD is the effective capture, analysis and application of data. But as companies generate and consume more data, they often struggle to turn those inputs into valuable information and insights. This challenge is real not only for pharmaceuticals but across every industry. "The advantage of more data is that ideally you'll be able to make more data-driven decisions," Owen says. "But companies have difficulty combining data in a way that makes sense. The danger is that data is taken out of context and used inappropriately."

jmp
Statistical Discovery.™ From SAS.

In particular, insights depend on contextual data, Owen believes. "We have more automation and more monitoring devices, and that generates more data," he says. "But we're often missing historical data and meta-data." Owen sees this data skills gap with his students, many of whom already have degrees in pharmacy or related fields. "If I give students an assignment in experimental design, they can generate a lot of data in a short period of time," he says. "But it doesn't necessarily have good data structure or standards applied to it."

Technology also has been a limiting factor. "One of the real problems I see in industry is the ubiquitous use of Excel," Owen says. The challenge is that different users will name data in different ways or store the same data in different places. "And when the metadata is changed to align data across studies, not everyone sees those changes. Then you don't have a single version of the truth."

Bringing data together in one place for positive outcomes

The solution for Owen, in his consulting work for real pharmaceutical clients through Insight By Design and with his students at De Montfort, is JMP software. JMP has become integral to the QbD program, where it's used to organize research data and to document and access the data students generate as part of assignments in experimental design. And Schlindwein agrees: "The use of JMP enables us to teach students how to organize research data, apply visualization and perform data analysis. Data management and data integrity are key within product development and manufacture."

Owen is especially excited about the Projects capability in JMP 14. Projects allows users to divide their desktops into zones for files, folders and virtual folders. Users can add reports, data tables, scripts, journals and even files in formats other than JMP. After they perform an analysis, the files appear in tabs. They can display multiple reports or graphs and run scripts from the Project. And importantly, the reports and graphs remain linked to the data table. "It's all interactive, so I can compare what happened in one table with another table," Owen explains. "A problem endemic to both academia and industry is having your data scattered all over the place, but with JMP, you can very quickly bring it all together."

In addition, as users create models or data visualizations, they can save the script of the data table to a journal. "Now you have a means of re-creating that analysis exactly in the future," Owen says. "And because the data can be arranged in tabs, you can see this sequential buildup of knowledge. Or you can create a dashboard view and present the same data in different ways, depending on the story you need to tell."

Historical and contextual data is key to QbD. "Quality by Design involves risk assessments," Owen says. "You need to know the frequency, the severity and your ability to detect a potential problem." In the past, stakeholders would ask experts what they remembered from past experience. "Today they ask, 'What data do you have to support this?'" Trustworthy data is equally important for regulatory compliance. "Regulators will come in and ask, 'How do you control this? How can you ensure the safety of patients?'" Owen explains. "Now you have a mechanism to say, 'Here are the potential risks, and these are the control strategies, and here's the data to support it.'"

But the greatest value for Owen is that JMP combines so many capabilities in a single tool. "Some programs might do experimental design well, but that's all they do," Owen says. "JMP has the table manipulation, it has the modeling, it has the visualization. It has all these things. You can actually use one package to do everything and organize the output."

Solution
Use data visualization and analytics in teaching Quality by Design (QbD), a systematic approach to optimizing all aspects of pharmaceutical product development.

Results
JMP® empowers De Montfort to collect and organize research data, apply visualization and analysis, and deliver essential QbD training to students who will graduate with valuable industry-ready skills.

To contact your local JMP office, please visit: **jmp.com/offices**

§sas

THE POWER TO KNOW®