QUALITY BY DESIGN
For the Pharmaceutical Industry – MSc/PG Dip/PG Cert (online)

The science and risk-based approach to pharmaceutical development and manufacturing technologies
In recent years, De Montfort University (DMU) has launched an innovative partnership with leading industrial corporations.

Senior professionals from more than 20 companies including AstraZeneca, Pfizer, GlaxoSmithKline, Bristol-Myers Squibb, Novartis Vaccines, MedImmune, and Baxter have been working alongside DMU's experts in Pharmacy education to deliver postgraduate training in Pharmaceutical Quality by Design. We work with a multi-disciplinary team with a fully integrated approach from companies represented by:

The term Quality by Design was first defined in the International Conference on Harmonisation (ICH) guideline Q8 Pharmaceutical Development (ICH, 2009) as follows:

“Quality-by-Design (QbD) is a systematic approach to development that begins with predefined objectives, emphasises product, process understanding and process control, based on sound science and quality risk management."

It is a holistic approach to pharmaceutical product development intended to modernise pharmaceutical manufacture.

Since 2011, using a flexible e-learning platform, we have been providing students with interactive, high quality learning materials, which have been specifically created as a unique collaboration between industry and academia.

Contact us – we will be delighted to discuss how our expertise in Quality by Design can help you and your company. E: qbd@dmu.ac.uk W: dmu.ac.uk/qbd
Outline
We offer unique training in Quality by Design (QbD) through our sustained collaboration with industry. This brings the methodology of successful science and engineering practices to the field of pharma.

This module is structured around a lecture series, delivered by industry professionals, all from leading companies, covering manufacturing and development, data analysis, processes, and regulatory considerations.

Delivery through our bespoke e-platform is completely flexible. A student is able to pace learning to suit individual timeframes, within the suggested timeline of 10 to 12 weeks. Lectures may be revisited, notes taken, and test results logged in each personal profile. The module is both immersive and interactive.

For employers, the module offers training in a flexible way. Students can develop their skills within their workplace environment.

Content
This module gives a general introduction to the four main areas: ICH guidelines including process validation and regulatory considerations, risk assessment, design of experiments, and process analytical – multivariate analysis as illustrated below:

These four areas give all students a practical understanding and approach to QbD in the pharmaceutical industry.

This module analyses the core QbD framework:

- Quality Target Product Profile (QTPP)
- Product and process development (Critical Quality Attributes – CQAs, Critical Materials Attributes – CMAAs and Critical Process Parameters – CPPs)
- Risk analysis
- Design space, control strategy and continuous improvement.

These principles are underpinned by science, pharmaceutical quality systems, quality risk management and knowledge management. This module introduces tools that facilitate the implementation of the QbD approach such as: process analysers; design of experiments; and multivariate analysis.
Who is teaching?

<table>
<thead>
<tr>
<th>Name</th>
<th>Company</th>
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<tbody>
<tr>
<td>Bruce Davis</td>
<td>Global Consulting</td>
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<tr>
<td>Dave Holt</td>
<td>AstraZeneca</td>
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<tr>
<td>Sean Hale</td>
<td>Consultant</td>
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<tr>
<td>Gerry Steele</td>
<td>PharmaCryst Consulting Ltd</td>
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<tr>
<td>Line Lundsberg</td>
<td>Lundsberg Consulting</td>
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<tr>
<td>Andrew Dennis</td>
<td>Bristol-Myers Squibb</td>
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<tr>
<td>Brad Swarbrick</td>
<td>CAMO Software AS</td>
</tr>
<tr>
<td>Ian Cox</td>
<td>JMP Division of SAS</td>
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<tr>
<td>Martin Owen, Kate Llewellyn, Gill Turner, Gustavo Marco &amp; Mustafa Zaman</td>
<td>GlaxoSmithKline</td>
</tr>
<tr>
<td>Claire Beckett &amp; Eric Johansson</td>
<td>MKS Umetrics</td>
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<tr>
<td>Richard Funnell</td>
<td>MHRA</td>
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On completion
The student will be able to:

- Understand the principles, origins and implementation of QbD within the international pharmaceutical industry and regulatory context;
- Understand and apply the principles of the overall QbD ‘process flow’ from QTPP to continuous improvement;
- Apply QbD thinking to ‘real life’ scenarios and case studies;
- Discuss the fundamentals of Risk Analysis and Quality Risk Management (QRM) tools and how they are used in practice during pharmaceutical development;
- Apply the principles of design of experiments to gain knowledge and increase the understanding of pharmaceutical product development and manufacturing;
- Discuss the role of process analytical technology in enhancing the levels of process understanding and process control;
- Demonstrate analytical thinking skills by evaluating relevant literature sources related to Quality by Design.

Who should attend?
This module is designed for graduates and postgraduates (biologists, chemists, chemical engineers, pharmacists, physicists, material scientists) who aspire to learn more about developing and manufacturing medicines using Quality by Design principles.

Cost
The cost of Regulatory Guidelines, Principles and Tools of Quality by Design is £1420 inc VAT.*

Special Offers
- Receive a 15% discount on the enrolment fees if you register for our Annual QbD Symposium*
- Receive a 10% reduction from the full price for the second and subsequent students from the same company*

*Terms and Conditions apply

Contact us
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Overview
We offer unique training in Quality by Design (QbD) through our sustained collaboration with industry. This brings the methodology of successful science and engineering practices to the field of pharma.

This module is structured around the QbD roadmap from quality target product profile through continuous improvement. The lectures are delivered by industry professionals, all from leading companies. The module also covers key areas that impact product or process design such as, API considerations, biopharmaceutics and excipient properties.

Delivery through our bespoke e-platform is completely flexible. A student is able to pace learning to suit individual timeframes, within the suggested timeline of 10 to 12 weeks. Lectures may be revisited, notes taken and test results logged in each personal profile. The module is both immersive and interactive.

For employers, the module offers training in a flexible way. Students can develop their skills within their workplace environment.

Content
This module gives a general introduction to the four main areas: design options, formulation and process development, design space, and control strategy. This also includes key areas which impact product or process design such as, biopharmaceutics, materials characterisation, excipient properties, and API considerations.

Who is teaching

<table>
<thead>
<tr>
<th>Name</th>
<th>Company</th>
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</thead>
<tbody>
<tr>
<td>James Kraunsoe, Talia Buggins &amp; Kathryn Gray</td>
<td>AstraZeneca</td>
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<tr>
<td>Roger Weaver</td>
<td>Pfizer</td>
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<tr>
<td>Mathias Walther</td>
<td>Pfizer</td>
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<tr>
<td>Elaine Stone</td>
<td>Merlin Powder Characterisation</td>
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<tr>
<td>Brian Carlin</td>
<td>FMC Biopolymer</td>
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<tr>
<td>Ian Robertson</td>
<td>Colorcon</td>
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<tr>
<td>Claire Beckett &amp; Erik Johansson</td>
<td>MKS Umetrics</td>
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<tr>
<td>Lloyd Stevens, Vanessa Zann, Zoe Kane &amp; Alison Connor</td>
<td>Quotient Clinical</td>
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</table>
On completion
The student will be able to:

• Evaluate the iterative nature of formulation and process design to meet the quality target product profile (QTPP);
• Have an awareness of the advantages of using a risk based approach, and prior knowledge to justify development decisions;
• Demonstrate skilful selection of key elements of formulation and process design applied to real industrial cases;
• Apply prior knowledge for the selection of excipients and critically justify their role in formulation design and efficient manufacturing;
• Understand how material properties impact formulation and process design;
• Understand and provide a reflective discussion of the importance of science and risk based approaches, including discussions with regulators, to ultimately provide benefits for the patient;
• Apply prior knowledge of design of experiments to demonstrate understanding of product development and process control to minimise variability;
• Discuss the role of biopharmaceutics in Quality by Design;
• Demonstrate how biopharmaceutics aids development, by showing the link between product performance and patient safety and efficacy.

Who should attend?
This module is designed for graduates and postgraduates (biologists, chemists, chemical engineers, pharmacists, physicists, material scientists) who aspire to learn more about developing and manufacturing medicines using Quality by Design principles.

Cost
The cost of The Quality by Design Product Development Roadmap module is £1420 inc VAT.*

Special Offers
• Receive a 15% discount on the enrolment fees if you register for our Annual QbD Symposium*
• Receive a 10% reduction from the full price for the second and subsequent students from the same company*

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Contact us
To receive information on more QbD modules please contact us: qbd@dmu.ac.uk or go to our website dmu.ac.uk/qbd
Overview
We offer unique training in Quality by Design (QbD) through our sustained collaboration with industry. This brings the methodology of successful science and engineering practices to the field of pharma.

This module is structured around practical industrial case study examples of the application of QbD principles and tools across a diverse range of product types.

The lectures are delivered by industry professionals, all from leading companies, covering key areas including film coating, inhalation products, freeze drying, sterile products, risk assessment tools, and analytical method developments.

Delivery through our bespoke e-platform is completely flexible. A student is able to pace learning to suit individual timeframes, within the suggested timeline of 10 to 12 weeks. Lectures may be revisited, notes taken and test results logged in each personal profile. The module is both immersive and interactive.

For employers, the module offers training in a flexible way. Students can develop their skills within their workplace environment.

Content
Practical examples will be given across a diverse range of product types such as inhalation, sterile products, and polymer excipients. The use of QbD principles in analytical method development will also be covered. This module will help learners identify how they can apply QbD principles in their work environment.

Who is teaching?

<table>
<thead>
<tr>
<th>Name</th>
<th>Company/Institution</th>
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<tbody>
<tr>
<td>Thomas Dassinger</td>
<td>Evonik Industries, AG</td>
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<tr>
<td>Andy Rignall</td>
<td>AstraZeneca</td>
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<tr>
<td>Paul Matejtschuk</td>
<td>NIBSC / MHRA</td>
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<tr>
<td>Matthew Brown</td>
<td>Lyosolutions</td>
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<tr>
<td>Pauline McGregor</td>
<td>PMcG Consulting</td>
</tr>
<tr>
<td>Tim Lukas &amp; Rachel Brody</td>
<td>Pfizer</td>
</tr>
<tr>
<td>Claire Beckett &amp; Erik Johansson</td>
<td>MKS Umetrics</td>
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On completion
The student will be able to:

- Evaluate how to apply the QbD principles to product development and manufacture using examples from industry;
- Make sound judgements on how science and risk based approaches can pinpoint the critical aspects of product development and manufacture using examples from industry;
- Describe rationally the challenges associated with implementing QbD in practice;
- Apply QbD thinking to ‘real life’ scenarios and case studies;
- Survey, retrieve, organise, and critically evaluate published relevant material from electronic and other sources.

Who should attend?
This module is designed for graduates and postgraduates (biologists, chemists, chemical engineers, pharmacists, physicists, material scientists) who aspire to learn more about developing and manufacturing medicines using Quality by Design principles.

Cost
The cost of the Quality by Design in Practice module is £1420 inc VAT.*

Special Offers
- Receive a 15% discount on the enrolment fees if you register for our Annual QbD Symposium*
- Receive a 10% reduction from the full price for the second and subsequent students from the same company*

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Overview
We offer unique training in Quality by Design (QbD) through our sustained collaboration with industry. This brings the methodology of successful science and engineering practices to the field of pharma.

This module presents the elements of QbD used in manufacturing, including advanced process controls as applied to both batch and continuous processing. Practical aspects of a QbD submission will be presented from the perspectives of author, assessor, and GMP inspector. Advanced manufacturing technology including real-time release and continuous quality verification are also presented.

The lectures are delivered by industry professionals, all from leading companies, covering areas including wet granulation, roller compaction, coating, process controls, principles of process scale-up, and continuous process verification.

Delivery through our bespoke e-platform is completely flexible. A student is able to pace learning to suit individual timeframes, within the suggested timeline of 6 to 8 weeks. Lectures may be revisited, notes taken and test results logged in each personal profile. The module is both immersive and interactive.

For employers, the module offers training in a flexible way. Students can develop their skills within their workplace environment.

Content
During this course, students will study process design as the initial stage of process development, creating a model of the commercial manufacturing process to include the intended scale of manufacturing. This module presents factors that need to be considered for the design, including facility, equipment, materials transfer, and manufacturing variables with particular focus on powder technology.

The selection of ‘type’ of process will depend on the product design and properties of the materials. Using current state-of-the-art techniques to support QbD principles in process development and optimisation of manufacturing, will be an important part of this module content.

Who is teaching?

<table>
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<tr>
<th>Name</th>
<th>Company</th>
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<tbody>
<tr>
<td>Trevor Page &amp; Jurgen Boeckx</td>
<td>GEA Pharma Systems</td>
</tr>
<tr>
<td>Keith Smith</td>
<td>Perceptive Engineering</td>
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<tr>
<td>David Holt &amp; Bindhu Gururajan</td>
<td>AstraZeneca</td>
</tr>
<tr>
<td>Penny Butterell</td>
<td>Pfizer</td>
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<tr>
<td>Richard Funnell</td>
<td>MHRA</td>
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On completion
The student will be able to:

• Evaluate how to apply the concepts of process control in manufacturing;
• Assess the use of advanced process control in manufacturing and the control of Critical Quality Attributes (CQAs) and Critical Process Parameters (CPPs);
• Make sound judgements on how a science and risk based approach to verification can pinpoint critical aspects of manufacturing;
• Review critically the current batch manufacturing process, including its limitations, and develop an understanding of the challenges faced by a shift to continuous processing;
• Continue to advance their knowledge and understanding of the application of continuous processing in manufacturing of pharmaceutical products;
• Understand the difference between a 'standard' and QbD regulatory submission, and how this might impact the assessment and inspection processes.

Who should attend?
This module is designed for graduates and postgraduates (biologists, chemists, chemical engineers, pharmacists, physicists, material scientists) who aspire to learn more about developing and manufacturing medicines using Quality by Design principles.

Cost
The cost of the Quality by Design in Manufacturing, Process Controls and Inspection module is £1000 inc VAT.*

Special Offers
• Receive a 15% discount on the enrolment fees if you register for our Annual QbD Symposium*
• Receive a 10% reduction from the full price for the second and subsequent students from the same company*

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Contact us
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Overview
We offer unique training in Quality by Design (QbD) through our sustained collaboration with industry. This brings the methodology of successful science and engineering practices to the field of biopharmaceuticals.

This new module is specifically designed for scientists working in the biopharmaceutical industry. It shows how the principles of Quality by Design can be applied to biopharmaceutical APIs and drug products.

The lectures are delivered by industry professionals, all from leading companies. We are working extensively with MedImmune in the development and planning of the module, and scientists from a wide range of companies, both Europe and US based, have contributed to the lectures. We also have regulatory contributions from the MHRA.

Delivery through our bespoke e-platform is completely flexible. A student is able to pace learning to suit individual timeframes, within the suggested timeline of 6 to 8 weeks. Lectures may be revisited, notes taken and test results logged in each personal profile. The module is both immersive and interactive.

For employers, the module offers training in a flexible way. Students can develop their skills within their workplace environment.

Content
This module introduces the application of Quality by Design to biopharmaceuticals through a series of case studies, which cover a diverse range of applications.
Who is teaching?

<table>
<thead>
<tr>
<th>Name</th>
<th>Institution</th>
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<tbody>
<tr>
<td>Sajal Patel &amp; Gisela Ferreira</td>
<td>MedImmune</td>
</tr>
<tr>
<td>M. Amin Khan, Cristiana Campa</td>
<td>Novartis Vaccines</td>
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<tr>
<td>Mikkel Nissum and Alexander</td>
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<td>Pysik</td>
<td></td>
</tr>
<tr>
<td>Keith Chidwick</td>
<td>MHRA</td>
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<tr>
<td>Bruno Boulanger</td>
<td>Arlenda</td>
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<tr>
<td>Lisa Hardwick</td>
<td>Baxter</td>
</tr>
<tr>
<td>Karen Bossert</td>
<td>Lyophilization Technology</td>
</tr>
<tr>
<td>David Paolella</td>
<td>GlaxoSmithKline</td>
</tr>
<tr>
<td>Sumit Luthra</td>
<td>Pfizer</td>
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On completion
The student will be able to:

- Understand the opportunities and challenges in applying QbD principles to biopharmaceutical drug substances and products;
- Describe the current status of QbD implementation within the biopharmaceutical industry and discuss the regulatory hurdles to be overcome in achieving wider implementation;
- Apply your knowledge of QbD concepts to the biopharmaceutical environment including QTPP, risk assessment, design of experiments, and multivariate analysis;
- Demonstrate an understanding of how advanced approaches such as PAT and multivariate analysis can enhance process understanding and facilitate the application of design space concepts to biopharmaceuticals;
- Understand how QbD concepts can be applied across a wide range of biopharmaceutical applications including the development and manufacture of biologic APIs, vaccines and freeze-dried products, as well as bioassay development;
- Apply QbD concepts to your own specialist area.

Who should attend?
This module is designed for graduates and postgraduates (biologists, chemists, chemical engineers, pharmacists, physicists, material scientists) who aspire to learn more about developing and manufacturing medicines using Quality by Design principles.

Cost
The cost of the Quality by Design for Biopharmaceuticals module is £1000 inc VAT.*

Special Offers
- Receive a 15% discount on the enrolment fees if you register for our Annual QbD Symposium*
- Receive a 10% reduction from the full price for the second and subsequent students from the same company*

*Terms and Conditions apply

Contact us
To receive information on more QbD modules please contact us: qbd@dmu.ac.uk or go to our website dmu.ac.uk/qbd
Outline
The module aims to introduce some generic research design principles and research methods in order to provide a thorough grounding in scientific areas of research, from experimental design, through data collection and presentation of data, to data analysis and the writing up of research results.

Delivery through our bespoke e-platform is completely flexible. The lectures are delivered by academic staff. A student is able to pace learning to suit individual timeframes, within the suggested timeline of 6 to 8 weeks. Lectures may be revisited, notes taken and test results logged in each personal profile. The module is both immersive and interactive.

Content
During this course, students will learn to apply methodologies including risk assessment, design of experiments (DoE), data collection, processing and analysis. The importance of design of experiments concept will be discussed. Issues are primarily illustrated through examples from industrial cases. Students are encouraged to share and draw upon their experiences in this module as part of the learning process.

Who is teaching?

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
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<tbody>
<tr>
<td>Walkiria Schlindwein</td>
<td>Principal Lecturer in Pharmaceutics</td>
</tr>
<tr>
<td>Irina Ermolina</td>
<td>Senior Lecturer in Pharmaceutics</td>
</tr>
<tr>
<td>David Armitage</td>
<td>Senior Lecturer in Pharmaceutics</td>
</tr>
</tbody>
</table>

On Completion
The students will be able to:

- Describe rationally the stages in the pharmaceutical research process.
- Select a research design appropriate to the research purpose.
- Design a research proposal with appropriate data collection and analysis tools.
- Provide a reflective discussion of the methodological basis of the research
- Demonstrate the accurate and consistent use of references
- Produce a clean and concise written style and good presentation
Who should attend?
This module is designed for graduates and postgraduates (biologists, chemists, chemical engineers, pharmacists, physicists, material scientists) who aspire to learn more about developing and manufacturing medicines using Quality by Design principles.

Cost
The cost of the Research Methods module is £1000 inc VAT.*

Special Offers
- Receive a 15% discount on the enrolment fees if you register for our Annual QbD Symposium*
- Receive a 10% reduction from the full price for the second and subsequent students from the same company*

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Overview
The purpose of this module is to provide students the opportunity to consolidate their knowledge of Quality by Design applied to pharmaceutical science or related industries by carrying out a research or development project in an area of their interest.

There are no video recorded lectures. Students will be assigned a supervisor that will support them throughout the project. They should by now have done most of the literature review as part of the research methods module and should be ready to start the project. The project work suggested timeline is between 15 to 20 weeks.

The dissertation will require the application of many elements of the skills and knowledge acquired in the other modules of the programme. Students will be expected to apply the knowledge they have gained across the modules to a real-life or simulated situation.

Content
The work will involve data collection and analysis. During this time, each student will be expected to gather data and to plan ongoing strategies for continued study.

The final dissertation should have around 15,000 words, excluding references and appendices and abstract. The report should be written in a scientific style.

Who is teaching?
Industrial supervisor with expertise in the subject area chosen by the student.

On Completion
The students will be able to:

- Clearly express a research problem or research purpose
- Select a research design appropriate to research purpose
- Demonstrate skilful selection and critical analysis of relevant literature
- Select methods of data collection and analysis appropriate to research design and purpose
- Provide a reflective discussion of the methodological basis of the research
- Present conclusions which are carefully discussed with reference to parameters of the research established earlier
- Produce evidence of original and independent thought
- Demonstrate the accurate and consistent use of references

Who should attend?
This module is designed for graduates and postgraduates (biologists, chemists, chemical engineers, pharmacists, physicists, material scientists) who aspire to learn more about developing and manufacturing medicines using Quality by Design principles.

Cost
The cost of the Quality by Design in Manufacturing, Process Controls and Inspection module is £2000 inc VAT.*

Special Offers
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