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QbD Approach in Analytical Method Development: A Review

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ABSTRACT

The new approach to pharmaceutical quality is Quality by Design (QbD). The goal of pharmaceutical production is to create a high-quality product and manufacturing process that consistently delivers the product's intended output. Quality cannot be measured into products; instead, it should be designed into them. It is an essential component of today's pharmaceutical quality management system. Throughout the design and production of a product, it is important to define the desired product performance profile [Target Product Profile (TPP), Target Product Quality Profile (TPQP)] and identify critical quality attributed to the product (CQA). We can design the product formulation and process to meet the product attributes based on this. This allows for the detection and monitoring of sources of uncertainty, as well as the effect of raw materials [critical material attributes (CMA)] and critical process parameters (CPP) on CQAs.

INTRODUCTION [1-6]

"Quality cannot be evaluated into the product, but it should be built into it," is the basic principle of QbD. The design space refers to the product's manufacturing environment, which includes the equipment, materials, operators, and manufacturing conditions. Before regulatory approval, the design space should be well established. Working in the design space is not considered a transition, but working outside of the design space is. When production takes place outside of the design space, various variables are tracked to see how they affect product quality. All of these variables will be evaluated, and conclusions will be drawn as a tool for QbD. The regulatory submission dossier contains all of this information. The data collected from product development studies can be used to improve the pharmaceutical product formulation. QRM will be based on the process variables that arise during the creation stages. Until beginning development studies, the product's QTPPs must be calculated, with the final product quality in mind, and an assessment conducted to achieve the desired product quality. Design space, requirements, and manufacturing controls are all included in the QTPP of a product.

Quality: Quality is an essential word in Quality by Design. As a result, quality is described as "norm or suitability for the intended use." This word encompasses qualities including identity, potency, and purity.

Quality by Design: The US Food and Drug Administration (FDA) and the International Council on Harmonization (ICH) have called for a variety of approaches to the production of pharmaceutical products and their subsequent manufacturing (ICH). Quality by Design (QbD) is a structured approach to production that starts with a predefined goal and emphasizes product and process understanding and process control, based on sound science and quality risk management.

The term "Quality by Design" (QbD) was coined to describe an approach to making the pharmaceutical industry more mindful of product quality, safety, and efficacy. The use of analytical instruments known as QbD has improved product quality (Quality by Design). From product creation to production, scientific methods may provide transparent and adequate information. By increasing performance and efficiency, these QbD tools can reduce the risk. The QbD method has been successfully implemented in traditional formulation production in recent years. For immediate and extended-release drug products, as well as biotechnological products, the USFDA has issued clear QbD guidelines. Regulatory agencies

are constantly recommending that ICH consistency standards such as Q8, Q9, Q10, and Q11 be implemented.

In the pharmaceutical industry, liquid chromatography (LC) is the most widely used separation technique, and high-performance liquid chromatography (HPLC), especially reversed-phase HPLC (RP HPLC), is one of the most widely accepted analytical techniques. To achieve quality in HPLC methods, QbD has become very relevant. For the implementation of QbD, robustness, and ruggedness in HPLC methods should be developed early in the method development stage to ensure method success over the lifetime of the product; otherwise, if a non-robust or non-rugged method is adapted, considerable time and resources will be needed to redevelop, revalidate, and retransfer analytical methods.

During the development phase, understanding essential process and product qualities, developing controls and tests based on empirical limits of understanding, and using the information gained during the product's life-cycle to operate in a continuous improvement environment. QbD refers to a pharmaceutical production strategy that focuses on formulation design and development, as well as manufacturing processes, to ensure that the prescribed product quality is met. Guidelines associated with mathematical models are used to ensure the autonomous and coordinated establishment and application of subject information. To ensure that the prescribed product quality is met, QbD refers to a pharmaceutical production strategy that focuses on formulation design and development, as well as manufacturing processes. To ensure the autonomous and organized establishment and implementation of subject material, guidelines associated with mathematical models are used. To establish an analytical method in a QbD setting, factors that affect robustness are considered. This system allows for continuous method improvement. In the literature, there are parallel possibilities for applying QbD to analytical techniques and manufacturing processes. It proposes approaches such as target profile, critical quality attributes (CQA), design space, and risk assessment, which can be applied to analytical methods as well. While not all pharmaceutical companies have embraced it, it has become mandatory by regulatory bodies and thus has a potential outlook. Because of the concept's numerous benefits and regulatory authority's ease of implementation, companies can follow it voluntarily. The Pharmaceutical Research and Manufacturers of America (PhRMA), the Analytical Technical Group (ATG), and the European Federation of Pharmaceutical Industries and Associations (EFPIA) all give simple ideas about how to apply QbD to analytical methods in parallel.

Advantages of QbD for industry:

1. If conditions change, the developed method will be more robust, resulting in a higher level of confidence.

2. It aids in better comprehension of the method.

3. When transferring a system from the study level to the quality control department, this technique has a higher success rate.

4. The design space principle eliminates post-approval modifications, which may result in a high price for all of the firm's products.

5. It offers room for the development of cutting-edge techniques through continuous improvement over the life cycle.

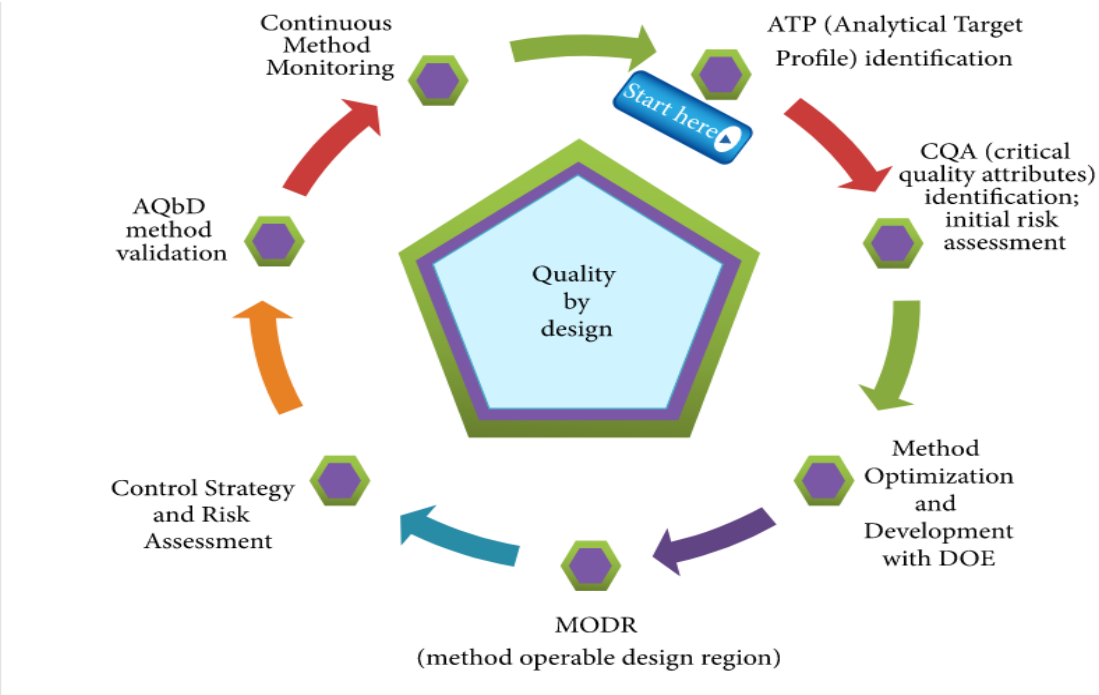

Figure No. 1:AQbD tools and life cycle

Regulatory aspects to QbD

FDA perspective [7]

In 2005, the USFDA requested that participating companies send CMC details showing QbD implementation as part of a New Drug Application. QbD entails a detailed understanding of the process, as well as the definition of an aim or purpose before the start of the process.

Other criteria for QbD implementation include design space and real-time release risk assessment. An international conference on harmonization in Q8 pharmaceutical growth, Q9 quality risk assessment, and Q10 pharmaceutical quality framework sets high standards for product quality. Process Analytical Technology (PAT), which is a Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance, is another way the FDA emphasizes the importance of pharmaceutical product quality. QbD ultimately aids in the implementation of Q8 and Q9. ‘‘QbD is a systematic approach to product and process design and production,” according to the FDA. FDA approved this definition in 2004, and a thorough outline was published in ‘pharmaceutical cGMPs for the twenty-first century – a risk-based approach.’

In nutshell,

- Designing efficient production processes ensures product quality and efficiency.
- Product and process requirements are based on empirical knowledge of how process variables influence product efficiency.
- Risk-based regulatory approaches are used to gain a scientific understanding of the product quality and performance process and to monitor it.
- Regulatory policies and measures that are related.

ICH guideline and QbD [2,3]

In the quality guidelines of the international conference on harmonization, ICH Q8 Pharmaceutical Development, ICH Q9 Quality Risk Management, and ICH Q10 Pharmaceutical Quality System, the underlying concepts of QbD, such as evidence- and risk-based product development, risk evaluation, lifecycle approach, and process design, are clarified.

Regulatory challenges and inspection [8]

The regulatory burden is less in a QbD concept, according to Anastasia G. Lolas and Anurag S. Rathore, since there are broader ranges and limitations based on product and process understanding. Changes within these ranges and limits do not need to be approved first.’

Inspections have traditionally been performed in conjunction with CDER’s Compliance Program “Inspection of Licensed Bio-logical Therapeutic Drug Products” and the FDA

system-based approach. However, in the current situation, where QbD is mandated, the question of how the inspection will take place arises. The FDA inspection team will evaluate the implementation and effectiveness of the process design as defined in the application, as well as whether expertise and risk management have been successfully transferred from production to manufacturing, during pre-license or preapproval inspections under the QbD definition. Throughout the product lifecycle, the inspection will assess the quality system's efficacy in terms of consistent product quality, change in control processes, process changes, deviation management, and information and risk management. Facility and equipment qualification and servicing, as well as raw material screening and supplier management, will all be carried out as before. However, programs that show robustness and accuracy in design, testing, and monitoring will be highlighted.

The flow of Quality By Design [1,3,9]

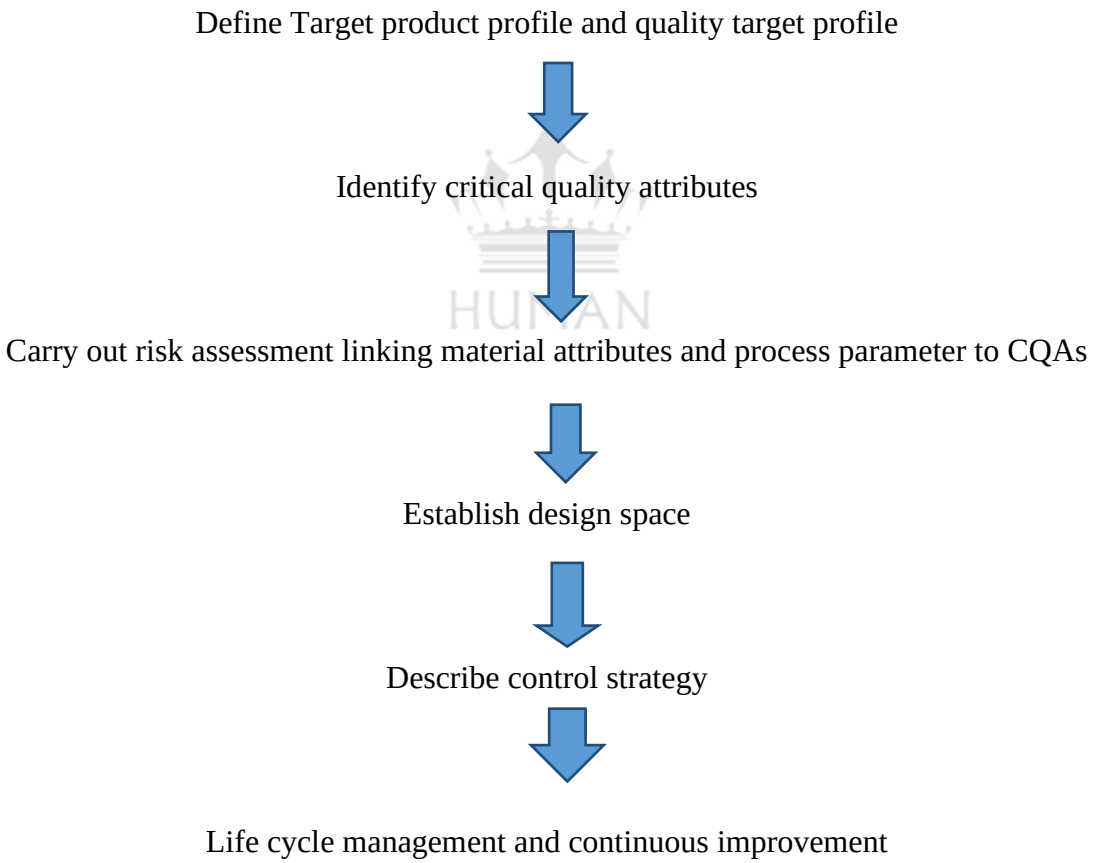

Figure No. 2: Flow of Quality by Design

Key Aspects of QBD [2, 3, 10]

Analytical target profile (ATP)

Since QbD is a systematic approach to product, process, and software creation, it starts with determining the method's target or purpose. ATP is a way for new method creation during this period of stress on goods and process understanding. It specifies the strategy specifications for system requirements that will be evaluated. The isolation, quantification, and detection of drug material, impurity, or degradant are usually the goals of chromatographic methods. Impurity is regarded as one of the most important consistency characteristics (CQA). It would be useful to know previous synthetic and manufacturing methods, as well as all alternate potential paths that lead to the encounter of impurities when dealing with traces of impurities. As specified in the ICH guideline, the method demand will be accuracy, precision, robustness, and so on. The QbD method, like the traditional method, requires detailed details about the analyte, such as its solubility, Pka, PH, UV 244 chromophores, and stability. These data rigorous method objectives were supported, as ATP can be set to obtain the best method. This gives method production a structure that aids in future planning. ATP follows the ICH guidelines to the letter. As a result, an Analytical Target Profile is the sum of all performance parameters needed for the intended analytical implementation, which guides the method creation process. For each of the characteristics listed in the management strategy, an ATP associate degree ATP will be created. The Analytical Target Profile specifies what the system must calculate and to what precision it must do so (Precision, accuracy, working range, sensitivity, and the associated performance criterion are examples of performance level characteristics.). Any approach that complies with the ATP is appropriate. At all points of the analytical life cycle, the ATP will be the focal point.

Critical Quality Attributes (CQA) [2]

First, factors that have a direct impact on product quality and safety are identified, and their possible impact on method creation is investigated. Understanding of the goods and process will be used to analyze CQA. If a drug product contains an impurity that has a direct effect on its consistency and safety, it is considered a vital quality attribute for the production of an HPLC method for that drug compound. Protection and effectiveness, according to Schweitzer *et al*, can be demonstrated by demonstrating observable regulation of quality attributes such as product specification, intermediate specification, and process control.

Quality Risk Assessment [1, 6, 9]

1. The risk to quality analysis should be focused on scientific knowledge and provide patient protection.

2. Outlines structured methods for assessing, controlling, communicating, and reviewing quality risks.

3. Applies over the products lifecycle, development, manufacturing & distribution.

4. The method mentioned in the ICH Q9 guideline are as follows-

5. Failure Mode Effects Analysis (FMEA);

6. Failure Mode, Effects, and Criticality Analysis (FMECA) is an acronym for Failure Mode, Effects, and Criticality Analysis.

7. Fault Tree Analysis (FTA);

8. Hazard Analysis and Critical Control Points (HACCP);

9. Hazard Operability Analysis (HAZOP);

10. Preliminary Hazard Analysis (PHA);

11. Risk ranking and filtering;

12. Supporting statistical tools.

Critical Material Attributes (CMA) and Critical Process Parameters (CPP) [6, 10, 11]

1. A material attribute is critical when a practical change in that attribute can significantly impact the quality of the output material.

2. CPPs are responsible for ensuring the CQAs & it is identified from a list of potential CPPs using risk assessment.

3. A process parameter is critical when it has a high impact on critical quality attributes.

Three categories for parameters or attributes:

a) Critical parameters:- A realistic change in parameter can cause the product to fail to get QTPP is a critical parameter.

b) Non-critical parameter:- No failure in QTPP determined within the potential operating space & no interactions with other parameters in the established suitable range.

c) Unclassified parameters: Unclassified parameters' criticality is unknown or unknown. To classify an unclassified parameter as critical or non-critical, additional data is required.

Risk assessment is a link between the input process variable and CQA. The following tools that have come under risk assessment are as follows:

1. Failure mode effect analysis (FMEA)
2. Ishikawa or fishbone diagram,
3. Pareto analysis.

After that, an FMEA can be used to rank the variables by risk and pick the process parameters with the highest risks for further research into their effects on Critical Quality Attributes. An Ishikawa or fishbone diagram is used to identify all possible variables, which include raw materials, instrumental factors, and environmental factors, all of which may affect CQA. For quantitatively distinguishing the effect of each problem on the chosen CAAs, Pareto charts were used. The identification and separation of compounds is the primary goal of chromatographic method production. Via risk assessment, the focus in the QbD approach is on rugged and robust methods.

Design Space [2]

Design space is described as a "multidimensional combination and interaction of input variables, a design space may be generated for a single operation, multiple operations, or the whole process (e.g. material attributes and process parameters) that have been demonstrated to provide quality assurance." According to FDA guidelines, defining design space is optional since product and process understanding can be defined without one. However, the above approach can aid in better understanding and overall system control.

Used of Design Space

1. The linkage between process inputs (inputs variables and process parameters) and critical quality attributes.
2. Used for one or more unit operation(s) or up to complete the process.

3. It can be used before or after MA.
4. Proposed by Applicant.
5. Working between the design spaces: not considered as a change.
6. Subject to regulatory approval and assessment.

Method development by QbD approach [12]

Step 1: Defining method intent

Since pharmaceutical QbD is a systematic, scientific, holistic, menace based and practical approach that begins with predefined objectives and emphasizes product and process understanding and control so the goals of HPLC method development have to be clearly defined. The eventual goal of the analytical method is to separate and quantify the main compound.

Step 2: Performing experimental design

Experimental design can be efficiently used for rapid and systematic method optimization. A systematic experimental design is considered necessary to aid in obtaining profound method understanding and performing optimization. It forms a chromatographic database that will help out with method understanding, optimization, and selection. In addition, it can be used to evaluate and implement the change of the method, should it be needed in the future, for example, should the chromatographic column used no longer be commercially available, or an impurity is no longer relevant.

Step 3: Evaluation of experimental results and selection of final method conditions

The conditions for the method need to be evaluated using the three-tiered approach. At first, the conditions should be evaluated for peaks symmetry, peaks fronting and peaks tailing. Later these conditions should be further evaluated by using more stringent criteria, such as tailing factor should be less than 1.5, etc.

Step 4: Performing risk assessment with robustness and ruggedness evaluation

Once the final method is selected against method attributes, it is highly likely that the selected method is reliable and will remain operational over the lifetime of the product. The fourth step of method development is mainly for the method verification and finalization and the

evaluation of method robustness and ruggedness to be carried out. A risk-based approach based on the QbD principles set out in ICH Q8 and Q9 can be applied to the evaluation of method robustness and ruggedness. Fishbone diagram such as structured methodologies for risk assessment can be implemented to identify the potential risk of the method due to a small change of method parameters or under a variety of conditions such as different laboratories, analysts, instruments, reagents, days, etc.

Table No. 1: Difference Between Traditional vs. QbD Approach [5, 10]

Traditional Analytical Method Development	**QbD (Lifecycle) Analytical Method Development**
Methods validated as a check-box tool as defined in International Conference on Harmonization (ICH) Q2 guidance, Validation of Analytical Procedure: Text and Methodology	Suitability of a method demonstrated against an analytical target profile, which defines the specific characteristics and criteria required by the process control strategy
Effect of variation in method parameters on performance of method is less understood	A science based structured approach for identifying and exploring method variables and their effect (method design and qualification stages)
Method transfer seen as separate exercise from validation	Method-transfer activities seen as components of the life cycle approach and considered change control exercises; appropriate method installation and verification actions determined by assessment (method performance verification stage)
The terms e.g.; method verification, method, method validation and revalidation are confusing in traditional approach	In lifecycle-approach more clear terms aligned with process validation and equipment qualification terminology are used
Method validation used to perform onetime event performed on completion of method development.	Method lifecycle validation used to performed all activities that ensure a method produces fit-for-purpose data during the whole lifecycle (i.e.; from development through to on-going routine operating environment and includes knowledge transfer from a sending unit)
Method transfer includes activities performed to transfer a method from sending unit to a receiving unit and do demonstrate equivalence between the two units	Method installation includes activities performed to ensure effective method set up in the routine operating environment and includes knowledge transfer from sending unit
Method verification involves ensuring pharmacopeial methods operate under the actual condition of use; revalidation is performed after changes for validation characteristics likely to be affected	Method performance verification involves demonstrating that a method performs as intended following a change in the methods operating conditions or operating environment

Applications of Quality by Design

1. For Chromatographic technique

a) In the determination of impurity

b) In a screening of column used for chromatography

c) In the development of HPLC method for drug products substance

d) In capillary electrophoresis

e) In stability studies

f) In UHPLC

2. For hyphenated technique

a) In LC-MS method development

3. In Bio-analytical method development

4. In dissolution studies

5. For spectroscopic measurement

a) In mass spectroscopy

b) In IR spectroscopy

c) In handling complex spectroscopic data

6. In modified-release products

7. In the tableting process

8. Nano suspension preparation

9. In the analysis of API and Excipients

10. In Biopharmaceuticals

1. For chromatographic technique

1.1. In the determination of impurity [13]

Gavin takes a quality-by-design approach to atomoxetine hydrochloride impurity method growth. For the analysis of atomoxetine hydrochloride, an ion-pairing HPLC method was developed, and associated device suitability parameters were investigated. To optimize conditions and demonstrate process robustness for the separation of atomoxetine and impurities, statistically planned experiments were used. Weiyong Li describes a three-step process development/optimization strategy for pharmaceutical HPLC assay/impurity methods, including multiple-column/mobile phase screening, further separation optimization using multiple organic modifiers in the mobile phase, and multiple-factor method optimization using Plackett–Burman experimental designs. Computer simulations were carried out using DryLab, a commercially available chromatography optimization program. The number of runs needed to create a method is greatly reduced using this method. When a satisfactory separation has been achieved, Plackett–Burman experimental designs are used to optimize the process as an example. Using advanced software and UPLC technology, a QbD with Design-of-Experiments approach was used to develop a chromatographic method for the separation of impurities in vancomycin. Traditional HPLC gradient methods can only isolate 13 of these impurities while using the QbD approach with a sub-2-pm ACQUITY UPLC Column, up to 26 impurities can be separated.

1.2. In a screening of column used for chromatography[14]

Describes the experimental design in detail, as well as the evaluation parameters used and some of the most widely used analytical columns from well-known column manufacturers. Seven RP-HPLC columns are evaluated using a standardized approach against predefined performance criteria. This method is an important part of the construction of a QbD method. The data created for frequently used columns aid practicing analysts in meeting the challenge of developing robust and rugged methods for use in a QbD environment. In UPLC, consistency by design has recently been used to investigate better column selection.

1.3. In the development of HPLC method for drug products/ substances [15, 16]

Monks *et al.* (2011) present a novel approach to developing high-pressure reversed-phase liquid chromatography (HPLC) methods using quality by design (QbD) concepts. Gradient time, temperature, aqueous eluent pH, and stationary phase are four typical critical parameters in HPLC that are evaluated using computer modeling software and a column database within the quality by design system. Figure 3: The interrelationships between components can be studied without comprehensive laboratory experiments using computer

simulation software, and preliminary optimized conditions can be obtained for each combination of column, pH, and organic modifier.

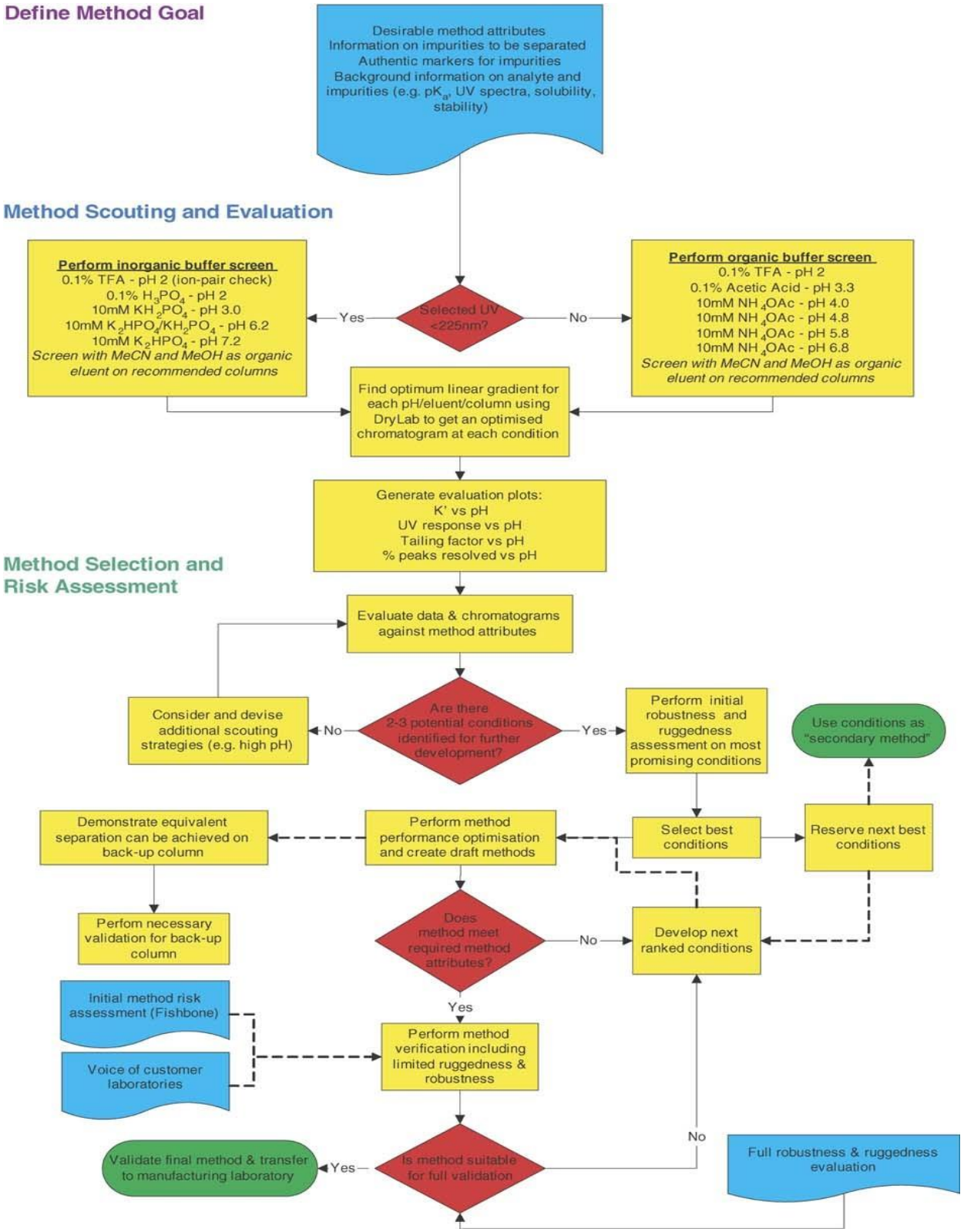

Figure No. 3: Flowchart for RP-HPLC MDS

Following the method selection, a risk assessment is carried out, followed by initial ruggedness and testing. The development of RP-HPLC impurity profile methods for pazopanib hydrochloride API, intermediates, and starting materials used the systematic MDS approach. Beyond good laboratory practices (equipment qualification/calibration, proper column maintenance, and general device suitability requirements), MSA and DoE studies of methods produced using the MDS failed to recognize any critical factor that would need to be tightly monitored. Finally, a database of process conditions was generated during the application of the MDS to the pazopanib hydrochloride RP-HPLC methods. From the beginning of the creation process, you can start building this database. This comprehensive database of suitable method conditions helps ensure that the scientific aspects of the method are well known by the time a project enters the later stages of growth, and theoretically allows for continuity if any future improvements to the method are required in QC laboratories.

In the development of an RP-HPLC impurity profile method for atomoxetine hydrochloride API, a complete MDS approach was also used. An analysis of the synthetic route and a tabulation of possible process impurities, intermediates, and starting materials that could carry through to the final API was used to determine the method target. One of these was a highly polar compound, while others were highly nonpolar, necessitating extra attention during method production. Following the discovery that a gradient RP-HPLC method would be needed to distinguish the known and expected impurities based on their polarity, scouting began. Under low pH conditions, however, scouting experiments with an RP-HPLC gradient system yielded troublesome peak shapes on several different columns. The scouting effort then shifted to solvent screening for an isocratic ion-pairing approach, which proved promising and was improved via a systematic column screening.

1.4. In capillary electrophoresis [17]

Experimental design and capillary electrophoresis for simultaneous study of arbutin, kojic acid, and hydroquinone in cosmetics were investigated by Yi-Hui *et al*. (2007). To improve the procedure, statistical parameters were used.

1.5. In stability studies [18]

The application of quality by design (QbD) principles to the creation of a stability-indicating HPLC system for a complex pain management drug product containing drug material, two

preservatives, and their degradants is defined by Karmarkar *et al.* (2011). The first approach had no resolution in drug degradant and preservative oxidative degradant peaks, as well as a preservative and another drug degradant peak. Fusion AETM software, which uses a DOE approach, was used to optimize the process. Within the operating space, the QbD-based method creation allowed the development of a design space and an operating space with specifics of all method performance characteristics and limitations, as well as method robustness.

1.6. In UHPLC [19]

Szabolcs *et al.* (2009) developed Rapid high-performance liquid chromatography with high prediction accuracy using design space computer modeling, demonstrating the accuracy of retention time prediction at high pressure (enhanced flow rate) and demonstrating that computer-assisted simulation can be useful for UHPLC applications with enough precision.2. For hyphenated technique.

2.1. In LC-MS method development [20]

The QbD approach to liquid chromatographic system creation is presented by Joseph Turpin. Present approaches to column screening in terms of experimental area, information space, design space coverage, data treatments to quantitation of the column screening experiment, and quantitative system robustness estimation are covered in three sections of the paper. (1) Primary effectors of separation are column type (column screening), pH, organic solvent type, and Gradient Time; (2) Secondary effectors of separation are pH, organic solvent type, and Gradient Time (Controls Slope) Pump flow, gradient conditions, temperature, and the ion-pairing agent are secondary effectors of separation.

3. In bioanalytical method development [21]

Torrealday *et al.* (2003) used an experimental design approach to optimize chromatographic variables that influenced the fluorescent response to establish an HPLC-fluorimetric bioanalytical tool for quantitation of telmisartan in urine. The central composite design was used to obtain the response surface from which the optimal conditions for the target response could be deduced, and the fractional factorial design was used to determine which of the studied variables affected the response.

4. In dissolution studies [22]

Miroslav *et al.* (2010) developed an HPLC procedure for measuring digoxin in dissolution samples, and the experimental design was used to demonstrate the robustness. Using a complete factorial design, the effect of minor changes in the acetonitrile fraction, mobile phase flow rate, column temperature, and column length on the characteristics of the digoxin peak was discovered (24). The presented HPLC method was used to assess the quality and stability of digoxin. Jun *et al.* (2011) used a quality-by-design approach to look at tablet dissolution shifts caused by accelerated stability using multivariate approaches. In addition, an article on quality by design case study was presented: Drug product and process creation using an integrated multivariate approach.

5. For spectroscopic measurements

5.1. In handling complex spectroscopic data [23]

In their analysis, Zengping *et al.* (2011) concentrated on Process analytical technology and real-time process monitoring of certain spectroscopic issues and challenges for understanding processes. Pharmaceutical and biotechnology companies are increasingly discovering and adopting process analytical technologies (PAT). To achieve this aim, detailed information must be extracted and knowledge gained from complex spectroscopic data. A variety of novel methods are demonstrated to address the limitations of current calibration/modeling methodologies, as well as a realistic system that would enhance the process control system's robustness and overall control strategy.

5.2. In mass spectroscopy [24]

Lianming and Frederick (2012) describe Practical prediction and existing challenges in quantitative chiral MS techniques for QbD (Quality-by-Design) based pharmaceutical applications in their study of recent developments in mass spectrometric methods for gas-phase chiral analysis of pharmaceutical and biological compounds.

5.3. In near-infrared [25,26]

A commentary on the Quality-by-Design (QbD) Approach to Quantitative Near-Infrared Continuous Pharmaceutical Manufacturing was presented by Mark (2011). Krause (2009) explains elements of the QbD theory to analytical methods in his study on QbD for Analytical Methods.

CONCLUSION

This review article help researcher to find the approach of QbD on the analytical method development. This article includes various parametric aspects of Method Development and the importance of application of the QbD approach to get a more accurate method. Also, this article focuses on the application of this type of approach in various areas of analysis.

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