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A Critical Review on Pharmaceutical Manufacturing Sciences

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ABSTRACT: ***The entire pharmaceutical industry desperately needs both creative technical solutions and fundamental research work to allow highly engineered drug products to be manufactured. The development of complex drug delivery systems (DDSs) on a commercial scale using existing technologies is difficult. This analysis covers essential elements of manufacturing sciences, starting with methods for risk management and experiment design (DoE) techniques. Where appropriate, experimental methods should be accompanied by analytical approaches. In this respect, state-of-the-art methods of mechanistic process modelling are listed in detail. The implementation of material science instruments paves the way for the processing of future DDSs on a molecular basis. A snapshot is presented of some of the existing tools. In addition, general engineering concepts that include process measurement and process control solutions are discussed. The last part of the review addresses future production solutions, covering continuous processing and, specifically, technology based on hot-melt processing and printing. Finally, issues are addressed relating to the application of these innovations as part of future health care systems.***

KEYWORDS: Drug, Material, Pharmaceutical, Solutions, System.

INTRODUCTION

The pharmaceutical and biopharmaceutical industries have historically not been precursors to revolutionary technical solutions and modern chemical engineering concepts. Manufacturing of drug products has been regulated for several decades by a regulatory system that safeguards the quality of the finished product and carries out batch-based processes, raw material and end-product characteristics, fixed process conditions and in-process material monitoring[1].

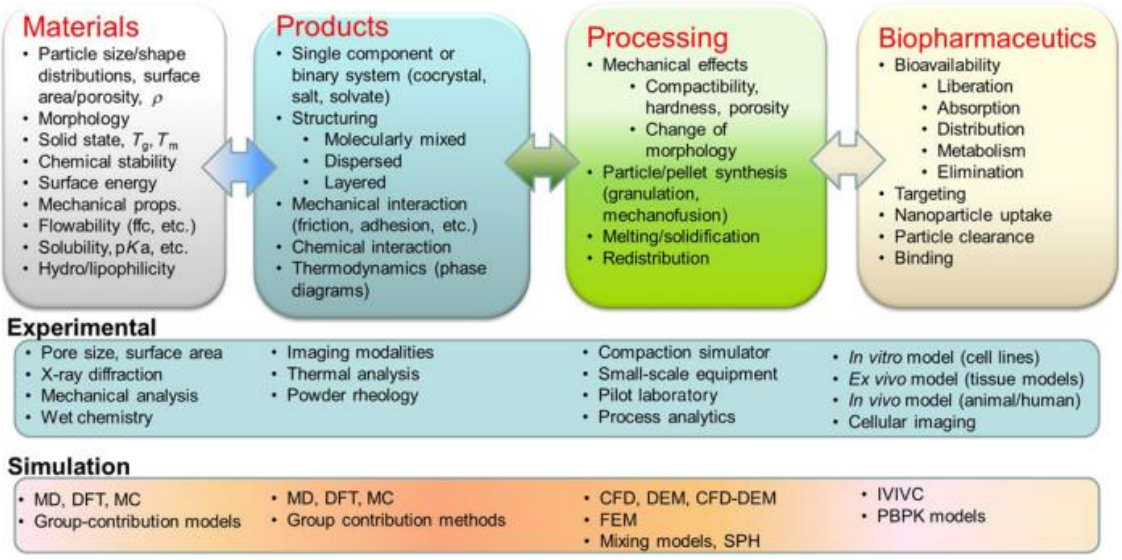

Figure 1: Illustrates the engineering view of pharmaceutical development[2]**.**

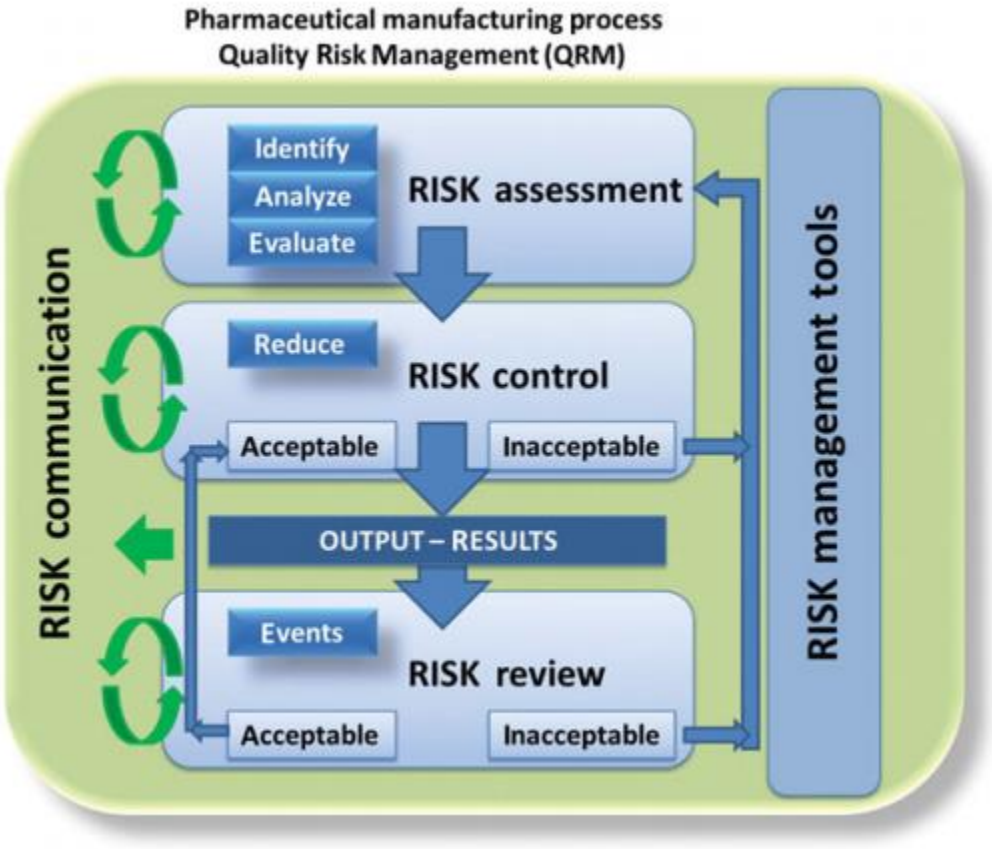

Figure 2: Illustrates the pharmaceutical quality risk management (QRM) system[3]**.**

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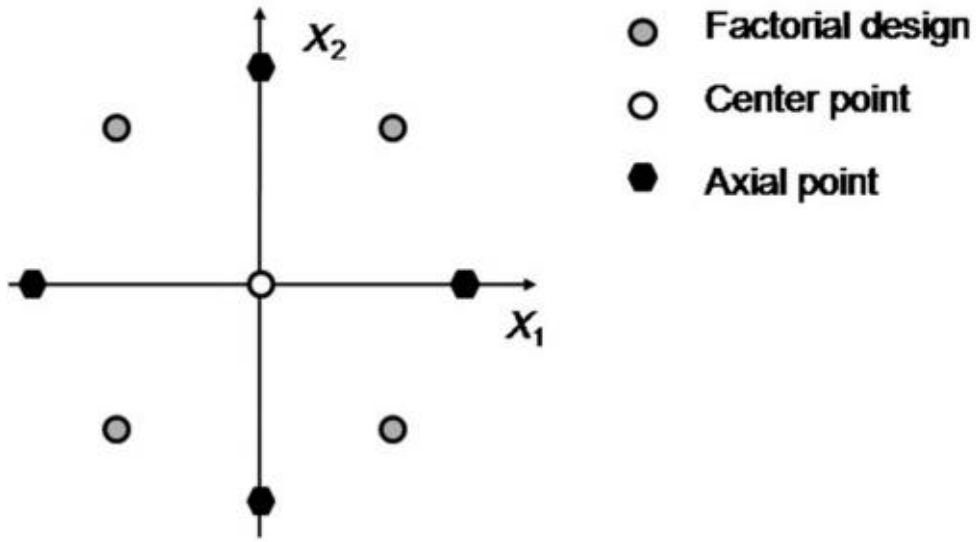

Figure 3: Illustrates the constructing central composite design (CCD) for (2) two variables[4]**.**

For the productivity of a pharmaceutical quality system, quality risk management is important as it ensures transparency over the life cycle of the product. In the manufacturing context, however, QRM today is limited not only by the selective (and often qualitative) usage of risk analysis techniques in the areas of certification, validation, service and maintenance, but also by existing approaches to risk communication[5]. In addition, the inaccessibility of information contained in paper records, locally stored archives and heads of workers is a limiting factor in modern QRM. Furthermore, QRM is only applied to particular aspects of growth or output. Life-cycle integrated QRM is largely absent. Figure 1 illustrates the engineering view of pharmaceutical development. Figure 2 illustrates the pharmaceutical quality risk management (QRM) system. Figure 3 illustrates the constructing central composite design (CCD) for (2) two variables[6].

DISCUSSION

Many pharmaceutical manufacturing operations deal with particles, especially in secondary (drug product) manufacturing. Powder blending, granulation, milling, roller compactation, tableting, and tablet coating are examples. The granular flows can be highly complex depending on the material's properties, containing randomly formed particles of different sizes, mechanical characteristics, and concentration. Although only continuum approaches have prevailed for many years (based on soil mechanics for quasi-static flows or on the kinetic theory of granular flows in the collision regime), new modelling techniques have recently become accessible to a wider community that enable particulate flows to be simulated mechanistically[7].

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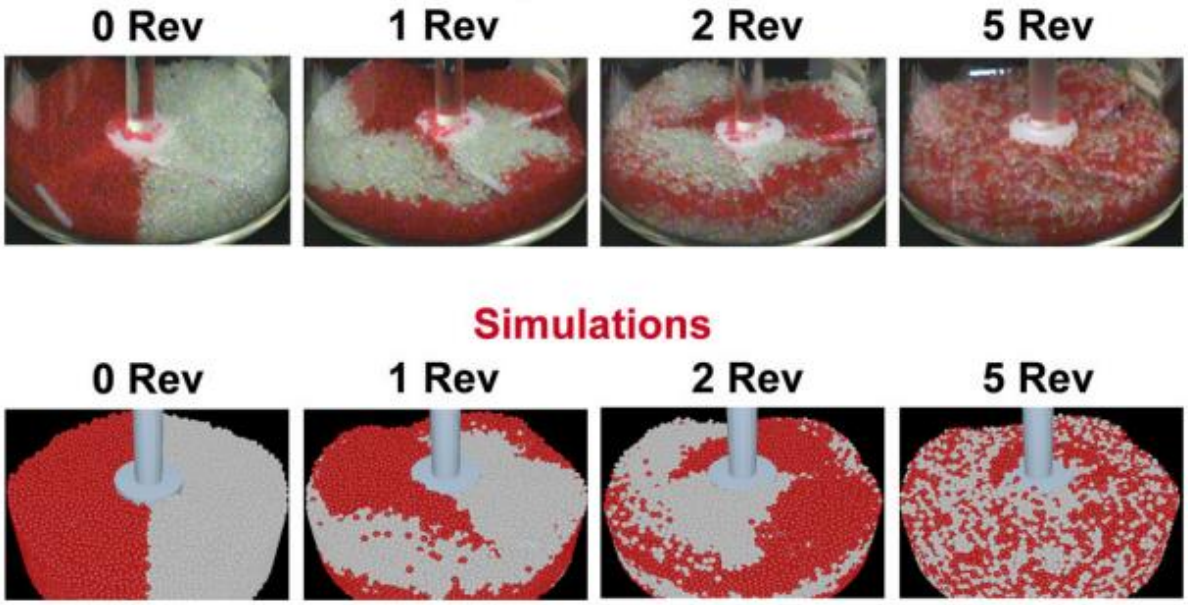

Figure 4: Depicts evaluation of experimentations and DEM simulations of a powder blending procedure of cohesionless particle[8]**.**

Linear (Newton's second law) and angular momentum balances in all three co-ordinate directions are solved for each particle in DEM simulations. Contact detection and the model of particle interaction that is used to measure the forces acting on individual particles during their collisions with other particles and/or walls are the most important aspects. Using the same contact model, each of these two contact types can be resolved and the material properties (Young modulus, Poisson ratio, restitution coefficient, and friction coefficients) for each contact type may vary, so that different materials can be modelled[9]. Figure 4 depicts evaluation of experimentations and DEM simulations of a powder blending procedure of cohesionless particle.

CONCLUSION

In this study, we give an introduction to the toolbox required for potential pharmaceutical manufacturing. It shows that substantial progress has been made in recent years, guided by improvements in the regulatory system and by stronger pharmaceutical and engineering science interactions. In addition, emerging differences have become more evident with regard to the logical creation of drug products and related production processes, ranging from the need to incorporate molecular, material and process models in a comprehensive computational context to the need for more sophisticated PAT tools for some applications. While it can be concluded that a great deal of basic knowledge and technical resources exist today to incorporate revolutionary principles of pharmaceutical manufacturing, further work is needed, particularly at the interface between pharmaceutical sciences and engineering, effectively defining a new discipline, that is, pharmaceutical engineering science. In short, the elements needed for the development of future high-tech pharmaceuticals have been established, gaps have been identified, and a concerted effort

by academia, industry, and regulatory experts to start implementing these concepts in practise will be the next step.

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