Certified Life Science Formulation Specialist

30 Oct - 3 Nov 2017 | 9am – 5pm

IMU Main Campus, Bukit Jalil, Malaysia

SYNOPSIS

In most solid formulations, the starting powdered materials are not usually presented in the ideal particle size for further processing. As a result, product content uniformity, subsequent processing speed and final product appearance may be affected. Granulation is often used to overcome these challenges. Whilst the principle of granulation is simple, the actual formulation development, selection of processing equipment and processing controls are a lot more complex. This is especially when specialised modified release or sustained release formulations are to be developed. This can pose a challenge to many formulators and pose confusing results if not properly understood,

Tabletting is the most common of oral solid dosage formulations. A well formulated tablet with assured content uniformity, consistent dissolution profile, good processing speed and an appealing appearance requires one to apply the knowledge of multiple sciences. Whilst the principle of tabletting is simple, the actual formulation development, selection of processing equipment and processing controls are a lot more complex. This can pose a challenge to many formulators and pose confusing results if not properly understood.
Firm grasp of the fundamental concepts in granulation and tabletting are important for a fulfilling career in this area even for those who are not formulators. For example a basic grasp of the subject area will enable a project manager to appreciate the technical challenge faced in the project or help an analyst to understand why the formulator insists on specific technical decision.

With this objective in mind, this course is designed to equip participants with both foundation knowledge and the practical aspects of granulation and tableting, and therefore increased interest and confidence for their future undertaking. The subject is delivered with minimal complex equations, stressing on practical day-to-day aspects faced instead.

Course Highlight

This course starts with essential fundamentals of granulation from pre-formulation. The participants taught the measurement theories of commonly-used sizing test equipment and equipment to pick up chemical interactions in pre-formulation. Once equipped with the essential concepts and measurement knowledge, the participants are then introduced to the operating principles of typical building blocks of a granulation formulation.
To conclude the course, an end-to-end walk-through of each stage of the granulation is demonstrated with various granulation, milling and sizing equipment. This serves to show the practical applications of the various subject areas learned in this course.

Next, we move to essential fundamentals of tabletting. The participants are then taught the principles of commonly used measurement equipment to assess the quality of the tablets eg hardness tester, friability tester and disintegration tester. Once equipped with the essential concepts and measurement knowledge, the participants are then introduced to the operating principles of typical building blocks of a tabletting formulation.

To conclude the course, an end-to-end walkthrough of each stage of the tabletting is demonstrated with various tabletting and tabletting related equipments. This serves to show the practical applications of the various subject areas learned in this course.

Prerequisite

Interest in formulation knowledge and desire to acquire better conceptual understanding in this area. Technical background in Science at Diploma or Degree level would be desirable.

Course Methodology

This course is presented classroom style in the first half of the day, with practical demonstration to illustrate the concepts taught in the afternoon.

What You Will Learn

- Essential fundamental concepts of granules
- Commonly-used particle sizing equipment measurement theories
- Operating principles and appreciation for typical building blocks of granulation such binders, disintegrant, technique of active addition, colour mixing etc
- Application of granulation concepts, measurements and formulation/ processing considerations, in end-to-end manner
- Essential fundamental concepts for of tablets
- Commonly-used tablet quality assessment equipment
- Operating principles and appreciation for typical building blocks of tabletting to overcome day-to-day challenges such as overcoming weak tablets, picking and sticking, chipped edges, low or high dissolution profile adjustments etc
- Processing condition considerations, in end-to-end manner

Who Should Attend

The primary target audience for this course is technicians and formulators/production managers involved in product design and development, production and validation of granulation and tabletted products.

This course is also applicable to a broad audience from various closely related area to granulation and tabletting who need to have strong basic understanding of the various concepts, terms and technologies, for example:

- Project Managers
- Analytical Scientists
- QC Managers
- Support and maintenance Engineers
- QA Engineers
- Validation Managers

Course Structure

1) Importance of Preformulation Activities	2) Importance of Sizing	3) Granulation	4) Milling
• Setting the correct user requirement specification (URS) before developing a tablet • Demo on poor URS causing unsatisfactory tablets • An initial assessment of ease of formulation based on URS (subjective approach) • An initial assessment of ease of formulation based on URS (objective approach) • Exercise to develop the URS limits for tabletting jointly with marketing. What is essential checklist. • Same size, different shape could behave very differently. • Choice of key measurement equipment, setting conditions to reflect the URS and the required observations • Recording and analysis of disintegration and dissolution profiles • Practical exercise to select the best combination of ingredients --- Baseline formulation • Setting down preformulations for stability	• Demo on mixing challenges in non-uniform size conditions • Same size, different shape could behave very differently • Choice of sizing equipment and selection • A feel for size (subjective approach) • A feel for size (objective approach) • Recording and analysis of sizing result • Making the final selection • Practical exercise to select the best combination of ingredients	• Basic formulation building blocks • Adjusting strength, size and shape of granules • Choice of granulation equipment and selection • Choice of drying equipment and selection • Practical exercise to develop the limits of formulation and operation of end-to-end of granulation • A feel for good end point of granulation, under granulation and over granulation (subjective approach) • A feel for good end point of granules (objective approach) • Recording and analysis of key parameters recorded (or under-recorded) • Making comments against the formulations developed and reviewing the key aspects	• Choice of milling equipment and selection • Practical exercise to demonstrate the limits of milling on strong and weak granules • A feel for good end point of milling (objective approach) • Recording and analysis of sizing result • Making the final selection of formulation

5) Troubleshooting Common Granulation Challenges	6) Tablet Formulation Development	7) Troubleshooting Common Tabletting Challenges	8) Workshop
• Is there a scale up limit? How do I adjust formulation accordingly? • Equipment transfer and validation challenges • Why occasional batch failures? • Rework possibility and batch records documentation • General maintenance	• Basic formulation building blocks • Adjusting strength, size and dissolution of tablets --- strategic plan mapping • Choice of tabletting equipment and selection • Choice of tooling and tooling design selection • Practical exercise to develop the limits of formulation and operation of end-to-end of tabletting • A feel for good tabletting control (subjective approach) • A feel for good tabletting control (objective approach) • Recording and analysis of key parameters recorded (or under-recorded) • Making comments against the formulations developed and reviewing the key aspects • Adjusting Tablet Formulation • Adjustment by excipient • Adjustment by equipment • Adjustment by active source • Practical exercise to demonstrate the limits of adjustments and relationship to preformulation • Recording and scoring of URS criteria to actual • Making the final selection of formulation	• Is there a scale up limit? How do I adjust formulation accordingly? • Equipment transfer and validation challenges • Why occasional batch failures? • Rework possibility and batch records documentation • General maintenance	• Going through end-to-end on pre-formulation • Going through end-to-end on granulation • Going through end-to-end on Tabletting dream CATCHER

Course Instructor

Dr. Leong Chuei Wuei

Summary of Experience
PhD in Pharmaceutical Technology with over 20 years of experience in the pharmaceutical industry in Asean and European settings. Vast technology and people management experience in senior positions.

Summary of Work
"Bench to Market" Product Lifecycle Management in Asean settings.
In Malaysia, part of a 3-person pioneering and core management team of Innovax, a commercial R&D lab for new pharmaceutical dosage development. Innovax is the only pharmaceutical R&D centre for the pharma division of CCM group of companies (a KLSE-listed company). CCM's pharma division is the biggest generic pharmaceutical player in Malaysia. The centre was responsible for all new product development, from feasibility, R&D project management, formulation and analytical method development, bioequivalent studies, product registration, scale up and commercial validation batches (inclusive of machine modification). The range of formulations covered included tablets, capsules, softgels, creams, emulsions, eyedrops and injectables. A key product, Omesec, won the Malaysian Product Innovation award in 2005 for its innovative production method that allowed it to be patented.

Setting New Benchmark as a Technical Solutions Centre
Under the management of the pioneering team, Innovax was recognised and respected as a technical solutions centre for all unresolved QC, manufacturing and registration issues from the various manufacturing sites within the pharma division.

Major operations issues resolved by Innovax that was personally led by me included :

- Successful validation of eyedrop filling line within the cleanroom after failure by the manufacturing team to qualify the system 6-months post renovation
- Unlocking 3 times more capacity in tabletting section by converting suitable wet granulation lines to direct compression. In so doing, also streamlined all facilities upgrade investment in tabletting section.
- Worked with the engineering team to successfully modify a capsule filling machine to fill minitablets by counting (rather than volume) to circumvent patent issues.
- Streamlining of product portfolio by ranking and creating a lifecycle management plan for each product within the companies, thus increasing profitability while maintaining output.

New Business Development Through Technical Investments
Innovax was also the technical centre for recommending and justifying all technical investments for CCM. Key investments recommended by Innovax was Impaxlabs, a Nasdaq-listed company, and Cardiome pharma, a Canadian company.

Production and Distribution CRO Management in European / Global setting for Clinical Trials
In The Netherlands, became part of the European R&D team for Astellas Pharma (one of the top 20 global pharma companies). Key role was as a clinical trial materials coordinator for Phase I to IV clinical trials. Responsible for management of Contract Research Organisations (CROs) for manufacturing and distribution of highly variable dosage forms and packaging designs. The prototype materials used for each clinical trial development (sometimes up to a million dosage units) are designed from first principle as these are often first-in-man products. Apart from management of arising issues internally and within CRO setups, the role also involved overcoming external regulatory challenges set by each participating country related to safety and quality in manufacturing and distribution. Countries involved were all countries in Europe, Nordic countries, Ukraine, Russia, Israel and the Middle East. Some trials were also involved North and South America, Africa and Australia.

This is a key role in a multidisciplinary set up reporting directly within function and indirectly across functional groups. Key information sharing with the correct emphasis and context to various regional offices within and across functional groups determines the correct focus of the trial.

Experienced in People Management through Difficult Times within Multi-cultural and Multi-disciplined teams In Asean, was the scientific team lead for all new company acquisitions in the pharma division of CCM. Hence, was involved in scientific due diligence and post acquisition reorganization.

In Europe, was the clinical trial materials team lead for the first series of three Astellas global trials managed out of Europe. Prior to this, the trials were managed regionally only, namely, Europe, Asia Pacific and America.