



JSS Academy of Higher Education & Research, Mysuru
(Deemed to be University – Accredited 'A+' Grade by NAAC)

JSS College of Pharmacy, Ooty
(An ISO 9001:2015 Certified Institution)

Department of Pharmacy Practice

Report on Alumni Interaction Series – 1

(Bridging the gap - Connecting to the World)

Name of the presenter:

Dr Sneha Ramanujam
Senior Formulation Scientist
Plasticon Healthcare
USA

Date: 26.06.2021

Title of the presentation:

Contract Manufacturing of Over-The-Counter drug products, nutraceuticals and sterile product formulations

Program Organized by:

Dept. of Pharmacy Practice
JSS College of Pharmacy, Ooty

&

Pharmacy Education Unit
JSS College of Pharmacy, Ooty

Alumni Interaction Series (AIS) is a new initiative of Dept. of Pharmacy Practice and Pharmacy Education Unit of JSS College of Pharmacy to connect the Pharm D students with the alumnus of our department with the quote “Bridging the Gap- Connecting to the World”.

This interaction series will provide an opportunity to the Pharm D and M Pharm (Pharmacy Practice) students to establish their professional connection with the alumnus of the institution and also understand the various topics dealt by the invitee. Further, this interaction will help to the students to better appreciate the various requirements for the academic learning including the pharmacotherapy knowledge, clinical case understanding to serve as clinical pharmacists in diverse patient care settings.

As patient care expert / specialist; our students have the responsibility to learn more from the working professionals which will help them to function as a member of a multidisciplinary health care team member and provide their services to the needy population.

With the aim, the first Alumni Interaction Series (AIS) was organized on the topic “Contract manufacturing of over-the-counter drug products, nutraceuticals and sterile product formulations” on 26.06.2021 for the benefit of our students.

Dr Sneha Soundharya, started her presentation with the definition of the term **Over-the-counter medicine** is also known as OTC or nonprescription medicine. All these terms refer to medicine that you can buy without a prescription. They are safe and effective when you follow the directions on the label and as directed by your health care professional.

Reading the product label is the most important part of taking care of yourself or your family when using over-the-counter (OTC) medicines (available without a prescription). This is especially true because many OTC medicines are taken without seeing a doctor. The OTC medicine label has always contained important usage and safety information for consumers, but now that information will be more consistent and even easier to read and to understand.

The U.S. Food and Drug Administration (FDA) has issued a regulation to make sure the labels on all OTC medicines (from a tube of fluoride toothpaste to a bottle of cough syrup) have information listed in the same order; are arranged in a simpler eye-catching, consistent style; and may contain easier to understand words. While the labels on a majority of OTC drug products will be appearing on store shelves soon, some products and companies have additional time to comply with the labeling regulations.

The makers of OTC medicines widely use tamper-evident packaging for their products. This is to help protect consumers against possible criminal tampering. Drug products with tamper-evident packaging have a statement on the packaging describing this safety feature. It is always important to inspect the outer packaging before buy an OTC drug product and to look at the product again before consume it.

Further, she also added about the label instructions for the OTC products:

Drug Facts	
Active ingredient (in each tablet)	Purpose
Chlorpheniramine maleate 2 mg.....	Antihistamine
Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy throat	
Warnings	
Ask a doctor before use if you have	
■ glaucoma ■ a breathing problem such as emphysema or chronic bronchitis	
■ trouble urinating due to an enlarged prostate gland	
Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives	
When using this product	
■ drowsiness may occur ■ avoid alcoholic drinks	
■ alcohol, sedatives, and tranquilizers may increase drowsiness	
■ be careful when driving a motor vehicle or operating machinery	
■ excitability may occur, especially in children	
If pregnant or breast-feeding, ask a health professional before use.	
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	
Directions	
adults and children 12 years and over	take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
children 6 years to under 12 years	take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
children under 6 years	ask a doctor

Drug Facts (continued)	▲
Other information ■ store at 20-25° C (68-77° F) ■ protect from excessive moisture	
Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch	

Nutraceuticals:

Nutraceuticals are products, which other than nutrition are also used as medicine. A nutraceutical product may be defined as a substance, which has physiological benefit or provides protection against chronic disease. Nutraceuticals may be used to improve health, delay the aging process, prevent chronic diseases, increase life expectancy, or support the structure or function of the body. Nowadays, nutraceuticals have received considerable interest due to potential nutritional, safety and therapeutic effects. Recent studies have shown promising results for these compounds in various complications.

In the US, the term “nutraceutical” products are regulated as drugs, food ingredients and dietary supplements. The term is not defined the same in different countries, but is usually defined as a product isolated from foods that is generally sold in medicinal forms not usually associated with food. Nutraceuticals, in contrast to pharmaceuticals, are substances, which usually have not patent protection. Both pharmaceutical and nutraceutical compounds might be used to cure or prevent diseases, but only pharmaceutical compounds have governmental sanction.

A dietary supplement is considered as a product that bears or contains one or more of the following dietary ingredients: A mineral, a vitamin, an amino acid, a medical herb or other botanical, a dietary substance for use by man to supplement the diet by increasing the total daily intake, or a concentrate, metabolite, constituent, extract, or combinations of these ingredients. Nutraceuticals are of these nutritional supplements which are used for health purposes other than nutrition. Some popular nutraceuticals include ginseng, Echinacea, green tea, glucosamine, omega-3, lutein, folic acid, and cod liver oil. Majority of the nutraceuticals possess multiple therapeutic properties.

Nowadays, nutraceuticals have received considerable interest due to potential nutritional, safety and therapeutic effects. A market research recently proposed that the worldwide nutraceuticals market is expanding and would reach US \$250 billion by 2018.

Recent studies have shown promising results for these compounds in various pathological complications such as diabetes, atherosclerosis, cardiovascular diseases (CVDs), cancer, and neurological disorders. These conditions involve many changes, including alterations redox state. Most of nutraceuticals have antioxidant activity with the ability to counteract this situation. Hence, they are considered as healthy sources of health promotion, especially for prevention of life threatening diseases such as diabetes, infection, renal, and gastrointestinal disorders.

Sterile Product Formulations:

Sterile product formulation development is more than just deciding which excipients to use with the given drug substance. The development of a sterile product requires that specific critical quality attributes be considered and evaluated, regardless of the route of delivery or the type of registration application.

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Further, she also added the overview of ICH Q8 Pharmaceutical Development requirements and Health Authority Quality by Design expectations with regard to raw materials, packaging, and manufacturing process. Each of the various stages of formulation and product development is then explored, from API characterization, formulation identification and development, stability and compatibility, process requirements, to patient in-use studies and other human factor considerations.

After the presentation, question and answer session was organized. Further, she added her experience in managing the various facilities of the manufacturing of OTC, nutraceuticals and sterile preparation including antibiotics and a special note was given by the invited speaker on the role of pharmacist's graduates at her company.

Dr. S. Ponnusankar thanked the speaker for spending her valuable time with our staff and students.

Dr. S Ponnusankar

Glimpses of the Event

26.06.2021 Alumni Interaction Series - Lecture 1 Dr Sneha Soundarya



CONTRACT MANUFACTURING OF OVER-THE-COUNTER DRUG PRODUCTS, NUTRACEUTICALS, AND STERILE PRODUCT FORMULATIONS

Sneha Ramanujam



26.06.2021 Alumni Interaction Series - Lecture 1 Dr Sneha Soundarya

Validate your processes

WHY?

- To obtain consistent, reliable and accurate results
- Act as a proof in decision making
- To get assurance of Quality product

Stages of Process Validation



WHAT TO VALIDATE?

- Systems
- Equipment
- Premises
- Test Methods
- Processes
- Facility



26.06.2021 Alumni Interaction Series - Lecture 1 Dr Sneha Soundarya

Preventive Maintenance

