BioZesta
A Quarterly Newsletter of Biocon Academy

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Biocon Academy
Adding Value, Enhancing Skills

MESSAGE FROM OUR PROGRAM DEAN

ROLE OF TECHNOLOGY IN EDUCATION

When I decided to talk about the role of Technology in Education, I thought, what better way to begin this article than by asking ChatGPT, an advanced conversational AI technology, to write us an introduction about it! Here's what ChatGPT had to say:

"Technology has had a profound impact on education, providing new opportunities for learning, teaching, and collaboration. It has revolutionized the way that students access information and learn, making it possible to deliver educational content anytime, anywhere. It has also provided teachers with powerful tools to enhance their teaching methods and track student progress, allowing for more personalized instruction and targeted interventions."

Well said chatGPT! Technology has drastically transformed the education sector by providing advanced teaching methods, improving accessibility, and enhancing student learning outcomes to name a few. In recent years, there has been an increased adoption of technology in education, such as ChatGPT, Augmented Reality (AR), Virtual Reality (VR), and Artificial Intelligence (AI) in classrooms. These technologies have redefined the traditional classroom experience, making learning more interactive, personalized, and engaging.

ChatGPT for instance, can be integrated into e-learning platforms, websites, and mobile applications. It provides personalized learning experiences by providing answers to students' questions, providing feedback on assignments, and offering learning recommendations. It has challenged the traditional teaching methods and the role of a teacher is getting redefined.

AR and VR technologies are also becoming increasingly popular in the education sector. These technologies offer students immersive experiences that enable them to explore the world around them in a more interactive way. Both AR and VR have been used to simulate real-life experiences in various fields such as healthcare, engineering, and architecture, making learning more practical and enjoyable. Now instead of reading about something in a textbook, you can actually put yourself in that situation, virtually. Exciting right?

AI technology has also played a significant role in the education sector. AI algorithms can analyze student performance data, identify learning patterns, and personalize learning experiences for individual students. That's right; AI can now be your personal tutor!

In conclusion, there is no denying that technology has transformed the face of education. If used aptly, these technologies can improve student learning outcomes, promote critical thinking, and prepare students for the demands of the modern workforce. As technology continues to evolve, the education sector must keep pace with the latest innovations to provide students with the best possible learning experiences.

- Bindu Ajit

DESIGN SPACE AND QUALITY BY DESIGN IN BIOPHARMACEUTICALS

*by **Satyanarayana S** Ph.D.*
Head of Program and Project Management,
Dr. Reddy's Laboratories Ltd.

From a regulatory perspective, the logical hierarchy of pharmaceutical product characteristics starts with "Safety" at the top, followed by "Quality" with "Affordability" being a distant third. Patient safety emanating from the use of the drug is always more critical than Efficacy/Quality. Process controls of "Safety" are usually the most audited and scrutinized aspects during an inspection, with a push towards automation, isolation and hands-free systems for safety assurance.

The Quality of products are an outcome of their manufacturing process and are usually unique to a product and a location. Specifications of product quality and methods used to determine batch-to-batch consistency are usually a subset of the methods used to establish efficacy at the time of the original regulatory filing. Thus, the snapshot on product quality, generated by the "lot release panel" of assays can only give us a limited view into the process followed for any specific batch. Products are the outcome of multifactorial processes in the cells and limited testing can only provide limited assurance on consistency of quality.

In a multifactorial environment inside and outside the cell, product characteristics are usually impacted by more than one factor and usually in a non-linear response. This is a fact recognized both by the manufacturer of the drug and by the regulators who approve the same for consumption. Traditionally, this variability in the manufacturing process is minimized via controlling critical process parameters across narrow ranges. While this has been a band-aid approach, with advances and miniaturization of instruments and an increasing expectation on control of quality by the regulators, a paradigm shift had to be arrived at in process development to address or improve process control in a cell derived product.

Since biopharmaceuticals are not comprised of a single species of molecules but are a population of highly related isoforms, varying in a few characteristics, the control of these characteristics is possible, by controlling those process parameters which have the greatest impact on these characters.

The second order control, which addresses. the multifactorial nature of the problem is through the identification of those interacting process parameters that govern each characteristic and studying their cumulative effect across the ranges of each individual process control. This higher order control where two or more process parameters impact a product characteristic refers to the often used term, "Design Space".

When multiple factors interact and govern a character, their cumulative effect is not necessarily predictable, some interactions are positive (a quantitative increase in a characteristic of a product) and some are negative (a quantitative decrease in a characteristic of the product). With multiple interactions, the effects become more fluid. To truly understand the interactions between the factors in play, pairwise studies with a matrix of set points of the individual control ranges can be evaluated. This would mean, for every factor that interacts with every other factor, interactions at every level of each factor has to be tested out. While this is possible, it is both tedious and limited in its output. This problem is solved by a statistical approach, wherein interacting factors (≥two) are varied across the range (levels) for each of the interacting factor and sampling of the ranges are used to derive the most likely outcome during the interactions. This selection of a subset of parameters to be tested, commonly referred to as "DOE- Design of Experiment", has the ability to predict the spectrum of possible interactions without performing every possible combination in the real world. A variety of designs have been developed but the specific choice is dependent on the problem being addressed.

Using a preliminary design to identify or screen for higher impacting factors followed by a more nuanced set of experiments for fewer factors helps reduce the experimental load while giving greater understanding of the interactions. The outcome of these statistical designs comes to life in the actual experiments carried out and are powered by the number of replicates and controls executed.The output of these experiments gives us the working ranges for each factor with a built-in interaction space and is referred to as the "Design Space" for the process, "a statistical space in which variation in the parameters has a very low probability of giving an output that is outside the desired range of product characteristics".

Process development has greatly benefited by the availability of miniaturized working models (e.g. AMBR in place of scaled up reactor) and the use of statistical tools that help identify experimental load. This approach, referred to as "Quality by Design", is becoming a standard expectation by both the regulators and industry management, as it leads to a higher success rate across batches serving both the safety aspects and the bottom line.

UPDATES

BIOCON ACADEMY CONDUCTED GRADUATION CEREMONY FOR 185 STUDENTS ACROSS FOUR PROGRAMS

Biocon Academy recently celebrated its seventh Graduation Day with 185 students graduating across four programs namely Biocon KGI Certificate Program in Biosciences, Biocon JSS AHER Certificate Program in Global Regulatory Affairs, Biocon Ramaiah Certificate Program in Quality Control Analytical, and BITS Biocon Certificate Program in Applied Industrial Microbiology.

The students were felicitated by Dr Kiran Mazumdar-Shaw, Chief Mentor, Biocon Academy & Executive Chairperson, Biocon and Biocon Biologics. The ceremony was attended by faculty members, industry experts, and mentors. Eight outstanding students who topped their respective batches were awarded 'Gold Medals for Academic Excellence'.

INAUGURATION OF BIOCON ACADEMY DEMO LAB

A newly set up demo lab at Biocon Academy was inaugurated by Kiran Mazumdar Shaw, Chief Mentor, Biocon Academy. This lab was supported by equipment generously donated by Thermo Fisher Scientific, Bürkert Fluid Control Systems, DD Enterprises, Syngene International, Biocon Biologics, JSS Academy of Higher Education and Research, and Ramaiah College of Arts, Science & Commerce. The entire lab furnishing was carried out and donated by Kewaunee.






UPDATES

SME OF THE YEAR AWARD - 2022

Our Chief Mentor, Kiran Mazumdar Shaw gave the 'SME OF THE YEAR 2022' Award to Mr. Rahul Jadav (Quality, Biocon Biologics) for his generous contribution in training our students of "Biocon KGI Certificate Program in Biosciences"

APPLIED INDUSTRIAL MICROBIOLOGY BATCH 9 & BIOSCIENCES BATCH 23 – CULTURAL DAY





A PATH TO UPGRADE YOUR KNOWLEDGE OF EMERGING INDUSTRY-SPECIFIC TECHNOLOGIES

First-of-its-kind initiative to empower Biotech Faculty from various educational institutes

ADMISSIONS OPEN

Biocon Academy Certificate Program in Faculty Development (FDP)

Batch IV

3rd July to 14th July, 2023 (10 days)

APPLY NOW

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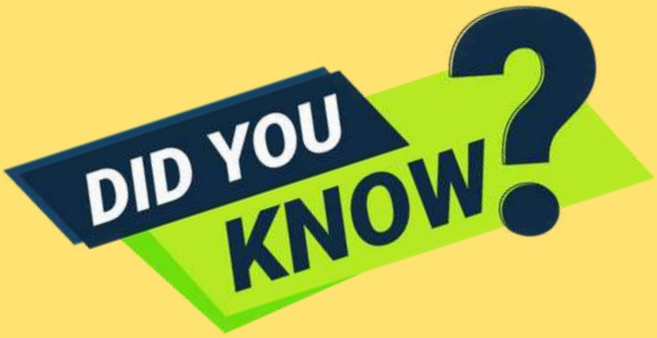
SARTORIUS TRAINING

Students of Biosciences Batch 23 got a unique opportunity to get trained on 'Biologics Process Development and Manufacturing' at Sartorius Stedim India Application Center, Bangalore.

Biocon Academy Newsletter Contest

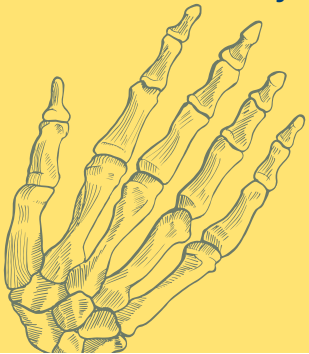
Scan the QR to participate in the contest

We organized a webinar in association with Biotecnika where our Academic Dean SS Easwaran spoke about "Biotechnology Careers Opportunities and Paths to Success". You can watch the recording of the live webinar here.



More than half your bones are located in your hands and feet

We are born with approximately 300 bones and cartilage which eventually fuse together by the time we reach adulthood. The adult human body consists of 206 bones. Of these bones, 106 of them are located in our hands and feet. Bones in the arms are among the most commonly broken bones and account for almost half of all adults' bone injuries.



Admissions Open

BITS Biocon Certificate Program in Applied Industrial Microbiology (Batch 10)

Biocon Ramaiah Certificate Program in Quality Control Analytical (Batch 5)

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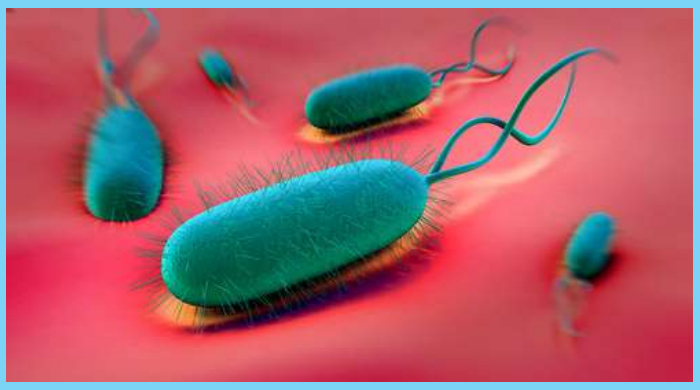
STUDENTS BLOG

CHOLERA TOXIN: THE TWO-EDGED SWORD

By Anamika, Biocon Certificate Program in Applied Industrial Microbiology, Batch 9



When we hear the term Toxin, the first thing comes to our mind is something which affects our health or a villain for us. But if I will say that a toxin can be a Hero too? Unbelievable! right?

In this article I will discuss about a toxin which has lethal effect but is considered as a very useful component in pharmaceutical industry which is Cholera Toxin.

CONTINUE READING

INDUSTRY-ACADEMIA INTERACTIONS

Dr. Vatsala G, Principal of Ramaiah College of Arts, Science & Commerce

Mr. Justin George Koottala, General Manager-Industry Engagements at BITS, Pilani

Dr. G R Naik, Hon'ble Vice Chancellor, Garden City University

Mr. Biswajit Banerjiee and Ms. Aditi Sharma from Biocon Talent Acquisition Team

KEEP UP WITH BIOCON ACADEMY

For suggestions and feedback, please write to us at **educonnect@bioconacademy.com**
Know more about us: **www.bioconacademy.com**

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