

PROFESSIONAL TRAINING

ACADEMIC YEAR: 2021-2023

Department: MSc Bioinformatics and Data science (2021-2023)

Course Title: PROFESSIONAL TRAINING

Semester: 2



COURSE COORDINATOR

DR.D. Alex Anand

Associate Professor

Department of Bioinformatics

SATHYABAMA INSTITUTE OF SCIENCE AND TECHNOLOGY

CHENNAI-600119

SUBMITTED BY:

SUBHIKSHA N IYER

MSc. BIOINFORMATICS AND DATASCIENCE-2020-2022

SATHYABAMA INSTITUTE OF SCIENCE AND TECHNOLOGY

CHENNAI-600119

DRUG DISCOVERY

DURATION:9HRS

OBJECTIVE:

- In this course you will learn the drug discovery process up to the filing of an Initial New Drug Application or IND. Each week you will learn the steps that a pharmaceutical or biotech company goes through to discover a new therapeutic drug.
- Understand the pharmaceutical and biotechnology market a changing landscape.
- Learn the major aspects of the drug discovery process, starting with target selection, to compound screening to designing lead candidates.
- Increase understanding of the various drug discovery tools and methods that are used for finding, identifying and designing a new drug.
- Define and understand the regulatory responsibilities for drug discovery to file an Investigational New Drug Application (IND).



DRUG DEVELOPMENT

DURATION:10HRS

OBJECTIVE:

- In this course you will learn the different stages of clinical development as well as the regulatory including but not limited to, an Investigational New Drug Application (IND), New Drug Application (NDA), and product labeling. Additionally you will learn how to Incorporate study design methods for consideration in the design of clinical protocols to assess safety, tolerability, and efficacy in multiple therapeutic areas.
- Phase 1 or early stage clinical trial are conducted primarily to determine how the new drug works in humans, its safety profile and to predict its dosage range. It typically involves between 30 and 100 healthy volunteers.
- Phase 2 or Proof of Concept POC studies test for efficacy as well as safety and side effects in a group of between 30 to 200 hundred patients with the disease for which the new drug is being developed
- Phase 3 or late stage clinical development involve much larger group of patients, between a few hundred to thousands, depending on the indication, which will help determine if the new drug can be considered both safe and effective. It will involve control groups using placebo and/or current treatment as a comparison.
- Product registration and approval process after a drug is considered safe and effective from Phase 3 trials, it must be authorized in each individual country before it can be marketed. All data generated about the small molecule or biologic is collected and submitted to the regulatory authorities in the US at the FDA, Food and Drug Administration FDA, in Europe the EMA or European Medicines Agency, Japan Ministry of Health and other countries which may require their own national approvals.

UC San Diego

Jun 10, 2022

Subhiksha Nagaraja

has successfully completed

Drug Development

an online non-credit course authorized by University of California San Diego and offered through Coursera

**COURSE
CERTIFICATE**



Williams Ettoati

Williams Ettoati, PharmD
Managing Director, Master of Science in Drug Development &
Product Management
Health Sciences Associate Clinical Professor
Associate Director, Center for Drug Discovery Innovation
Director, Education Innovation Support Team
Office of The Executive Vice Chancellor
University of California San Diego
Skaggs School of Pharmacy and Pharmaceutical Sciences

Joseph D. Ma

Joseph D. Ma, Pharm.D.
Associate Professor
Skaggs School of Pharmacy & Pharmaceutical Sciences
University of California, San Diego

Verify at:
<https://coursera.org/verify/8HVD4TWRWMHY>
Coursera has confirmed the identity of this individual and their
participation in the course.

DRUG COMMERCIALIZATION

DURATION:11HRS

OBJECTIVE:

- This course will cover pharmacoeconomic, marketing strategy, intellectual property strategy, portfolio management, managed markets and strategic alliances. It will also have a lecture case study from startup to success.
- These are conducted after a new drug has been approved by the regulatory agencies and launched.
- This enables new treatment uses for the new drug to be developed, comparisons with other treatments for the same indication to be made, and determination of the clinical effectiveness of the new drug in a wider variety of patient types, and more rare side effects, if any, may be detected .



DRUG DEVELOPMENT AND PRODUCT MANAGEMENT

OBJECTIVE:

Pharmaceutical and biotech companies are spending years and millions of dollars developing drugs or promising new biologics, all with the hopes of saving or enhancing patients' lives. This specialization will provide you with a bird's-eye view of the entire process of drug discovery and development process



3 Courses

Drug Discovery
Drug Development
Drug Commercialization



Jun 10, 2022

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has successfully completed the online, non-credit Specialization

Drug Development Product Management

Pharmaceutical and biotech companies are spending years and millions of dollars developing drugs or promising new biologics, all with the hopes of saving or enhancing patients' lives. This specialization will provide you with a bird's-eye view of the entire process of drug discovery and development process. In the first course you will begin with learning how scientists go from selecting a drug discovery target to filing an Initial New Drug application (IND). In the second course you will then learn the intricacy of drug development from Phase 0 to Phase 3 clinical trials and filing a New Drug Application. Finally, in course three, the specialization will provide you an understanding of the complexities in launching new pharmaceutical products and ensure sales success.

The online specialization named in this certificate may draw on material from courses taught on-campus, but the included courses are not equivalent to on-campus courses. Participation in this online specialization does not constitute enrollment at this university. This certificate does not confer a University grade, course credit or degree, and it does not verify the identity of the learner.

Joseph D. Ma
Joseph D. Ma, Pharm.D.
Associate Professor
Skaggs School of
Pharmacy &
Pharmaceutical
Sciences
University of California,
San Diego

Williams Ettouati
Williams Ettouati,
PharmD
Managing Director,
Master of Science in
Drug Development &
Product Management
Health Sciences
Associate Clinical
Professor
Associate Director,
Center for Drug
Discovery Innovation
Director, Education
Innovation Support
Team
Office of The Executive
Vice Chancellor
University of California
San Diego,
Skaggs School of
Pharmacy and
Pharmaceutical
Sciences

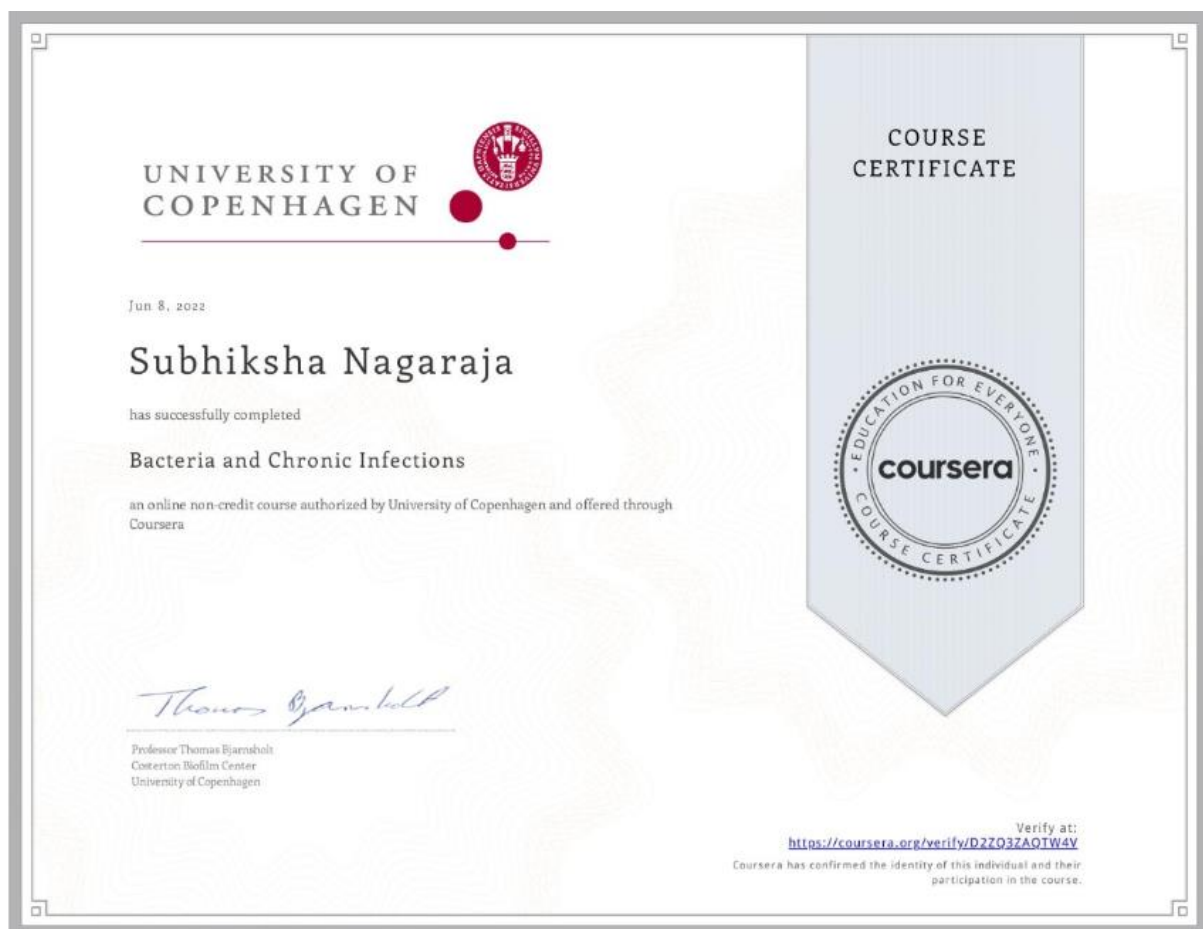
Verify this certificate at:
<https://coursera.org/verify/specialization/7QK97EKHLZJL>

BACTERIA AND CHRONIC INFECTIONS

DURATION:10HRS

OBJECTIVE:

This course will give you an introduction to bacteria and chronic infections. Leading experts in the field will make you familiar with the fundamental concepts of microbiology and bacteriology such as single cell bacteria, biofilm formation, and acute and chronic infections.



WHAT IS DATA SCIENCE

DURATION:10HRS

OBJECTIVE:

This course will give you The importance of data science is based on the ability to take existing data that is not necessarily useful on its own and combine it with other data points to generate insights an organization can use to learn more about its customers and audience.

