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Challenges in Fermentation scale up process for production of new chemical entities: from discovery to clinic

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Abstract

Microbes are prolific sources of novel secondary metabolites with a range of biological activities that may ultimately find application as anti-infective, anti-cancer agents or other pharmaceutically useful compounds. Hence many drug discovery companies are engaged in isolation of novel bioactive metabolites from these microbial sources. Till date, numerous metabolites from these sources have been identified and few of them are undergoing developmental process through pre-clinical or clinical stages or have been launched in the market.

Many of such new secondary metabolites are produced using microbial fermentation process rather than chemical synthesis because the fermentations are economically competitive and produce biologically active isomers. To carry out further drug development work including pre-clinical and clinical trials, sufficient quantities of these compounds are needed. For this purpose, the processes are usually scaled up from flask to pilot scale fermenter level. The scale up process is very challenging as the conditions followed during shake flask or lab fermentation may not suit for high volume cultivation. The recovery of the product is also a difficult job and needs lots of efforts to arrive at the right process conditions. Also, at the initial stages of discovery, the microbial strains (wild type) generally have very low production yields of the desired novel metabolites when cultivated in flasks or laboratory fermenter. In order to make the scale up process cost effective, the strains need to be improved to achieve several fold improvement in titers.

This presentation will describe the challenges faced during fermentation scale-up process for production of new chemical entities with reference to some case studies. A successful process would lead to commercialization of newly discovered molecule in future.

Biography

Prafull Ranadive has done his masters degree in Microbiology from University of Mumbai and PhD in Biotechnology from VIT University in India. He is holding a post of Group Leader in Natural Products Department (Fermentation Technology Group) of Piramal Enterprises Ltd., Life Science division, a premier drug discovery research organization in India. He has around six publications and two patents on his name. He has given presentations on Bioprocess related subjects in national and international conferences. He has more than 20 years of experience in the field of Fermentation Technology, Strain improvement, Industrial Microbiology, Microbial strain isolation and characterization, Bio-processing and New Drug Discovery. He has handled more than 13 commercial technologies on fermentation process and scaled up to pilot and production scale. In discovery segment, he has handled several scale-up projects and established large scale process for mainly two new antibiotics.