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Abstract

Manufacturing Avenues and Challenges in Gene Modified Cell Therapies

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Abstract:

We are currently living in the era of gene modified cell therapies. The field is moving with an exponential pace as multiple clinical trial data is showing promising results and global regulatory agencies like EMA, FDA have approved considerable number of products in recent time. The typical autologous CAR-T manufacturing involves isolation of specific immune cells (T cells) at clinical site, then in the laboratory, these cells are reprogrammed with genetic information that turns them into programmable cellular assassins and then grown in numbers in vitro over 2 weeks. These cells are then infused back into patient intravenously. While the idea is alluringly simple, the development, manufacturing under cGMP and clinical delivery are exceedingly complex. The important requirement of cGMP (current Good Manufacturing Practices) for this treatment, including graded controlled infrastructure, cGMP compliant raw material as well as cGMP supportive documentation and assurance is enforced by global regulatory authorities The manufacturing and quality control requirements are cost and skill intensive. There are multiple platforms been developed towards manufacturing of the personalized medicine including the semi-integrated and fully integrated platforms. The application of HIV derived lentiviral vector is also the core to the process. The current talk will feature the manufacturing avenues for CAR-T cell therapy and the challenges therby.

Biography:

Hemant Dhamne, obtained his Ph. D from the ACTREC, Mumbai (2014) in Applied Virology. His Ph.D. thesis was on the Lentiviral Vector Mediate Long Term Expression of Therapeutic Proteins. He completed his doctoral work in the labs of Dr. Robin Mukhopadhyaya and Dr. Rajiv Kalraiya. His doctoral studies mainly focused on developing the novel LV platform using the inhouse HIV-1 derived vector system and its application for cell engineering and tumor targeting in pre-clinical

models. From 2014 to 2015, he was a post doctoral fellow in the laboratory of Dr. Amit Dutt in the same institute working on functional genomics aspects spanning novel miRNA discovery and novel mutations in cancer causing genes and associated pathways. Thereafter, he joined Gene Therapy Division at Intas Pharmaceuticals, Ahmedabad. He worked on early stage product development of AAV mediated gene therapy for diseases such hemophilia, neuronal and eye disorders. He successfully developed the pilot scale manufacturing platforms using suspension cell lines in upstream and chromatography in downstream process. He also contributed for assay development. He served as Research Scientist from 2015 to 2017 and as Senior Research Scientist from 2017 to 2019. He also developed early stage designs and assays for CAR-T research.

Publication of speakers:

1. Upadhyay, Pawan & Gardi, Nilesh & Dhamne, Hemant & Sonawane, Kavitha & D'Cruz, Anil & Nair, Sudhir & Dutt, Amit. (2015). Abstract 5161: Discovery of a matrix metalloproteinase MMP10 as a clinically relevant biomark¬er to predict lymph node metastasis in tongue squamous cell carcinoma. Cancer Research. 75. 10.1158/1538-7445. AM2015-5161.

2. Dhamne, Hemant & Chande, Ajit & Mukhopadhyaya, Robin. (2013). Lentiviral vector platform for improved erythropoietin expression concomitant with shRNA me¬diated host cell elastase down regulation. Plasmid. 71. 10.1016/j.plasmid.2013.11.001

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