Univerza v Ljubljani

Fakulteta za kemijo in kemijsko tehnologijo

p.p. 537, Večna pot 113 1001 Ljubljana telefon: 01 479 80 00 faks: 01 241 91 44 dekanat@fkkt.uni-lj.si



VABILO NA PREDAVANJE V OKVIRU DOKTORSKEGA ŠTUDIJA KEMIJSKE ZNANOSTI

dr. Gorazd Hribar

Lek Pharmaceuticals d.d.

z naslovom:

Trends in manufacturing of biologics: from batch to continuous

v sredo, 23. marca 2016 ob 15:00 uri v predavalnici 1 v 1. nadstropju Fakultete za kemijo in kemijsko tehnologijo, Večna pot 113

Vljudno vabljeni!

Povzetek

My lecture will cover the field of manufacturing of biologics, starting with short description of biological drugs and biosimilars and later focusing on manufacturing of largest group of biologics - monoclonal antibodies (MAbs). Currently biologics/biopharmaceuticals are by far the fastest-growing part of pharmaceutical industry and they generated global revenues of around \$160 billion in 2014, making up about 20 percent of the pharma market. Since the accessibility of such drugs is still limited due to extremely high costs and there is growing competition on the market, there is the need to produce biologics in a more efficient way. Therefore new approaches are developed and transferred from other types of industry. The current typical process for producing biologics, especially MAbs, is a fed-batch bioprocess, followed by purification sequence, which contains several chromatographic steps done in batch mode and some intermediate steps in-between (such as virus removal steps, filtrations, concentrations). However the trends are moving to a more continuous process. This means implementation of different steps in complete manufacturing sequence. For bioprocess part trend is to implement high-density perfusion bioprocess and for purification several techniques are implemented, including multi-column chromatography and different flow-through templates. All this enables shifting of manufacturing from large scale bioreactors and large chromatography columns, to a more efficient smaller scale production. The new concept is rather to scale out and use smaller equipment, than to scale up.