

Degree project for Master of Science at BioLamina, Sundbyberg

BioLamina in Sundbyberg is a Swedish biotech company with global clients within research, biotech and pharma. We are a growing team of more than 60 people working within production, R&D, quality and customer service. BioLamina produces and develops premium laminins, which are proteins used in e.g., stem-cell research and cell therapy development. Our quality system is developing, and so is the entire company, and we're striving to work according to GMP within a few years. The company has a certified quality system according to ISO 9001:2015.

About the degree work

Biotechnological products follow strict regiments of low endotoxin levels, and often use the same guidelines and regulatory framework as biological medicines¹. There are several compendial methods traditionally used to determine the endotoxin levels in a finished product, intermediates and in process controls, and these assays need to be validated to ensure that the methods produce accurate and reproducible results. Many assays use or are derivatives of the traditional method using amoebocyte lysate from the horseshoe crab (*Limulus polyphemus* or *Tachypleus tridentatus*), while several new artificial assays exist or are being developed in the industry. The traditional LAL-method have known limitations where natural (1,3)- β -D-glucan, a natural polysaccharide found in some fungi, plants and bacteria, can interact and interfere with the assay producing false positive results.

Job assignment

You will perform comparison studies of at least three different commercial and compendial methods² to determine endotoxin levels, to identify possible sources of interference and any relationship between these. These studies will be performed on our finished products, intermediates and in process controls during the production cycle of BioLaminins, with samples that have different grades of purity.

¹ European Medicines Agency, ICH Q4B Annex 14 Bacterial endotoxins tests

² European Pharmacopoeia, 2.6.14 Bacterial endotoxins

Degree project goals

- Perform comparison studies between the recognized and compendial methods between LAL methods and rFC (recombinant factor C) for endotoxin detection
- Investigate, analyze, and identify possible sources of interference and any relationship between endotoxin level and interference
- Determine the most suitable method to determine endotoxin levels in BioLamina's finished products, intermediates and in process controls

Who are you?

You are at the end of your Master of Medical Science within the Life Sciences, drug development or pharmaceuticals in an accredited higher education in the European Union. Courses and knowledge that are important to have for this degree work to be successful is biochemistry, microbiology, general analytical laboratory techniques and experience working with eucaryotic cells, a working knowledge of statistics and excellent English language skills, both spoken and written.

Other information

The degree work is for 30 ECTS credits (20 weeks) during the spring of 2023. Placement is in Sundbyberg, a close suburb to Stockholm (ca 6km from Stockholm city), with excellent commuting opportunities (bus, tram, subway and train).

For any questions about the degree work, please contact Dr. Fatemeh Madani at [fatemeh.madani\(at\)biolamina.com](mailto:fatemeh.madani@biolamina.com), project supervisor, or Dr. Harald Eriksson [harald.eriksson\(at\)biolamina.com](mailto:harald.eriksson@biolamina.com), recruiting manager.

About Biolamina:

BioLamina AB is a Swedish based Biotech company that originates from scientific innovations at Karolinska Institute. Our main products are recombinant laminins, human proteins that are being used to maintain and expand pluripotent stem cells and other primary cell types and for subsequent differentiation into different specialized cell types. BioLamina is revolutionizing cell culture and our products are being used by researchers to develop cell therapies, building on the era of regenerative medicine. Founded in 2009, BioLamina has grown organically and today we are a team of more than 60 people who develop, produce, market, and sell cell culture research reagents to academic and industrial clients globally.

For more information, please see: <http://www.biolamina.com>