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Subject : Proposal for an internship at UCB PHARMA for 2018

(Belgium, UK, Switzerland, Ireland)

By E NORRANT

Please find subject for internship at UCB Pharma for 2018 on the:

- **research centers based Braine l'Alleud in Belgium close to Brussels**
- **research centers based Slough in UK (Close to London)**
- **manufacturing plants**
  - **in Braine (Belgium),**
  - **Bulle (Switzerland)**

Website http://www.ucb.com/

UCB Pharma :

A global biopharma focused on severe diseases with operations in approximately 40 countries and global revenue of € 3.4 billion in 2014.

- **We combine biology and chemistry to make major breakthroughs.** By integrating our expertise in large, antibody-based molecules and small, chemically-derived molecules, we can offer families with severe diseases and their specialist physicians the advantages of both large and small molecules to produce extraordinary breakthroughs.
- **We partner with the leaders in the pharmaceutical industry.** The complexities of severe diseases are beyond the expertise and resources of a single organisation. That is why we have teamed up with partners - we play to our strengths and tap into the organisations with greater or complementary strengths

Development of sustained-release formulations for the subcutaneous administration of biotherapeutics

Job description

The aim of the project consists in developing sustained-release formulations for the subcutaneous administration of biotherapeutics.

Due to the relative low bioavailability observed when biotherapeutics are administered by noninvasive routes (e.g. oral route), such biomolecules are commonly parenterally delivered. However, using conventional parenteral dosage forms, frequent injections are required to maintain the drug concentration into the therapeutic window due to the reduced serum half-times of proteins. This may induce lack of patient compliance as well as peaks and valleys effect in blood levels due to multiple dosing. That is why development of sustained-release formulations has been intensified over the past few years.

These controlled-release systems must meet several criteria. For instance, they should be characterized by high drug loadings to allow the administration of therapeutic doses as well as by a continuous and sustained-release profile over time. These formulations should also maintain the physicochemical stability of the proteins through both production and delivery to avoid immunogenicity issues.

The strategy chosen for this project is the encapsulation of the biomolecule into a polymeric matrix. Indeed, this method allows the protection of the encapsulated biomolecule against degradation as well as its controlled release over time. In order to produce the sustained-release formulations, the spray-drying of a water-in-oil (w/o) emulsion was selected for this project. Spray-drying is a one-step process that is reproducible and easily scalable. Moreover, compared to double emulsions techniques, the spray-drying of a w/o emulsion avoids the presence of an external aqueous phase and it can therefore lead to the production of microparticles with higher drug loadings.

So far, this encapsulation process has been applied to one full-length monoclonal antibody. In order to evaluate the possibility of creating a delivery platform using this method, other biological compounds with different characteristics should also be tested.

Besides, “real-time” release of biological compounds from these sustained-release systems can last for months which is a limitation for the proper development of these formulations. Furthermore, the method that is currently used to evaluate the *in vitro* release of biological compounds from the sustained-release formulations is not really representative of the *in vivo* release Thus, it would be interesting to develop on one hand, an accelerated release test and on the other hand, an *in vitro* test that would represent in the closest way possible the *in vivo* release of biotherapeutics.

In this context, the internship will be divided in two parts:

The first part will consist in:

- applying the encapsulation process to two other biological compounds: peptides and an antibody fragment
- performing a complete characterization of the produced formulations: morphology, particles size, release profile, stability of the compound inside the formulations, etc…
- optimizing the formulations according to the results obtained

The second part will consist in:

- developing an accelerated release test that would be predictive of the “real-time” release test and that would be able to differentiate different formulations
- developing an *in vitro* release test based on the *in vivo* data already available for the sustained-release formulations of one antibody

Contract:

Minimum 5- 6 months full time

Indemnity (750€/month)

Adress of the Site :

UCB Pharma

Avenue de l'industrie

1420 Braine-L'Alleud, Belgium

Started date :

February or March 2018

Profil of student

He or she should :

- have knowledge of different analytical methods (HPLC, particle size analysis,…) especially in biological compounds characterization
- have a good knowledge in pharmaceutical development
- have good oral and written communication skills
- speak and write in English

Manager with email and phone number:

Sarah Marquette

Principal Scientist in Biological Formulation Development

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Driven by science.