

Chief Manufacturing and Development Officer

The role is described as Chief Manufacturing and Development Officer and it is a senior role (one of 4 Group Managers) reporting to the CEO.

The manufacturing element is the production of materials (cells, cell secretome, purified product from secretome, and extracellular vesicles (EVs)) for (i) process development and optimisation (ii) product evaluation and (iii) product sales.

There are three other Group Managers at present - Dr Chris Baldwin (Commercial and including Innovation Group), Ms Pohlee Chan (Corporate), Ms Alison Mew (Manufacturing & Development – Interim) and Dr Gregor Lichtfuss (Futures).

The role has 4 direct reports at present, Cell and cell processing (Upstream), Purification (Downstream), Analytics (Process and Product) and Evaluation (Product Testing). The group has a total of around 19 people in it at present. The Group will grow further. This Group is our core – really important!

Deliverables include:

- Process readiness
 1. commissioning and operationalisation of a new GMP manufacturing cleanroom facility and Quality System at our Lab at The Baker in CY '21 (already underway)
 2. biologic manufacturing processes further optimised, characterised and standardised
 3. development of appropriate analytics to use in process optimisation, product evaluation and characterisation
 4. undertaking further optimisation and development of the DSP process steps/equipment/reagents
 5. various product CMC packages prepared over time
 6. bringing the manufacturing process and product standardisation of Cevaris product to the point that it is 'clinical trials-ready'
 7. bringing the manufacturing process and product standardisation of Plexaris product to the point that it is 'sales-ready'
 8. adding appropriate equipment and resources to the Group
 9. establishing Exopharm as a world leader in full scale (challenging) EV manufacturing and EV products
- Product development and supply
 1. clinical trial underway with Cevaris under CTN and/or IND in late CY '21 or early CY'22
 2. various biologic (exosome) products (including Plexaris, Cevaris and various EEVs) further optimised, characterised and standardised
 3. supporting Innovation Group's work (manufacture, analytics and testing) and supporting patent/knowhow expansion with the provision of analytics and data
 4. supporting regulatory submissions for clinical trials and product approvals
 5. ready supply of EV products of various types

- Leadership
 1. provide direction and guidance to the team to ensure milestones and agreed KPIs are met
 2. developing the people within the team
 3. external communications – limited participation in ‘deals’ discussions and investor meetings
 4. working with Commercial (deal doing) and Corporate (finance etc) to further the strategy and milestones of the company
 5. keeping the CEO, Board and other Group Managers informed.

The person we need is:

- A credible process expert who fills internal and external leadership roles:
 - highly experienced with considerable ‘domain knowledge’ in many aspects of biologics manufacture and products. Understands own limitations and can leverage industry contacts to fill technical gaps.
 - directing staff to focus on the ‘main game’ activities/outcomes (and avoiding distractions and nice-to-do things)
 - high reliability
 - good communicator, clear communication up, down and sideways
 - international experience would be welcome.
- A can-do person:
 - able to see the big picture and innovate, but also able to get down to the detail and try things to see what works. Not overly theoretical.
 - thoughtful but practical and hands-on if needed. High levels of drive and determination. But not a ‘maniac’.
 - able to multi-task – can lead the team to deliver parallel work stream (A + B + C ... not A then B then C)
- A “small company person” with a desire to build:
 - high levels of personal contribution – not just an administrator or planner. This is a person who makes things happen, and knows what is happening and why.
 - ability to harness skills and strengths in the team and create a set of common goals
 - flexible and adaptable
 - willing to take risks and make decisions, able to cut corners with consideration and care
 - a team player disinterested in politics

The person will have industry experience and likely (i) a PhD or (ii) Masters and other plus (e.g. MBA). This is much more a ‘manufacturing’ and development role than a scientific role – (note: there are high levels of ambiguity and uncertainty and much ‘breaking new ground’)

We need a very capable, experienced person who can be agile and flexible. We are open to a younger person who can grow quickly.