



# PCI Pharma Services Brexit update CPhI 2018

## Current status of Brexit

PCI Services is currently planning for a hard Brexit meaning that should the UK government trade negotiations not result in any agreement and the UK is entirely outside the European framework following the 29th March 2019 date, it is anticipated that materials QP released within the UK will not be recognized by the European Union. This will mean that products will need to be tested within an EU facility to allow QP release for use within EU member states.

As a result, the following will be required:

- EU finished product testing on EU importation for commercial products;
- EU QP release for EU supplies;
- UK QP release for UK supplies;
- Regulatory authority approvals in place for QP release, testing and distribution activities.

## The PCI Pharma Services Plan

The PCI Brexit Plan is currently progressing at pace and will be updated on receipt of further guidance relating to policies between the UK government and European Union in relation to pharmaceutical trade and supply.

As a proactive contingency measure, PCI acquired an EU based pharmaceutical outsourcing supplier in September 2017 located near Dublin, Ireland, to ensure a PCI continued presence within the EU single market. This strategic acquisition provided the foundation for PCI's post-Brexit plans and the commitment to ensure continuity of European supply for all existing and potential new customers, irrespective of the trade agreement that is reached. As a result of this planning, PCI will continue supply as per present arrangements utilizing our EU and UK sites as appropriate.

The PCI Ireland facility is currently undergoing the required modifications to support the supply, testing and release of products into the EU. This includes:

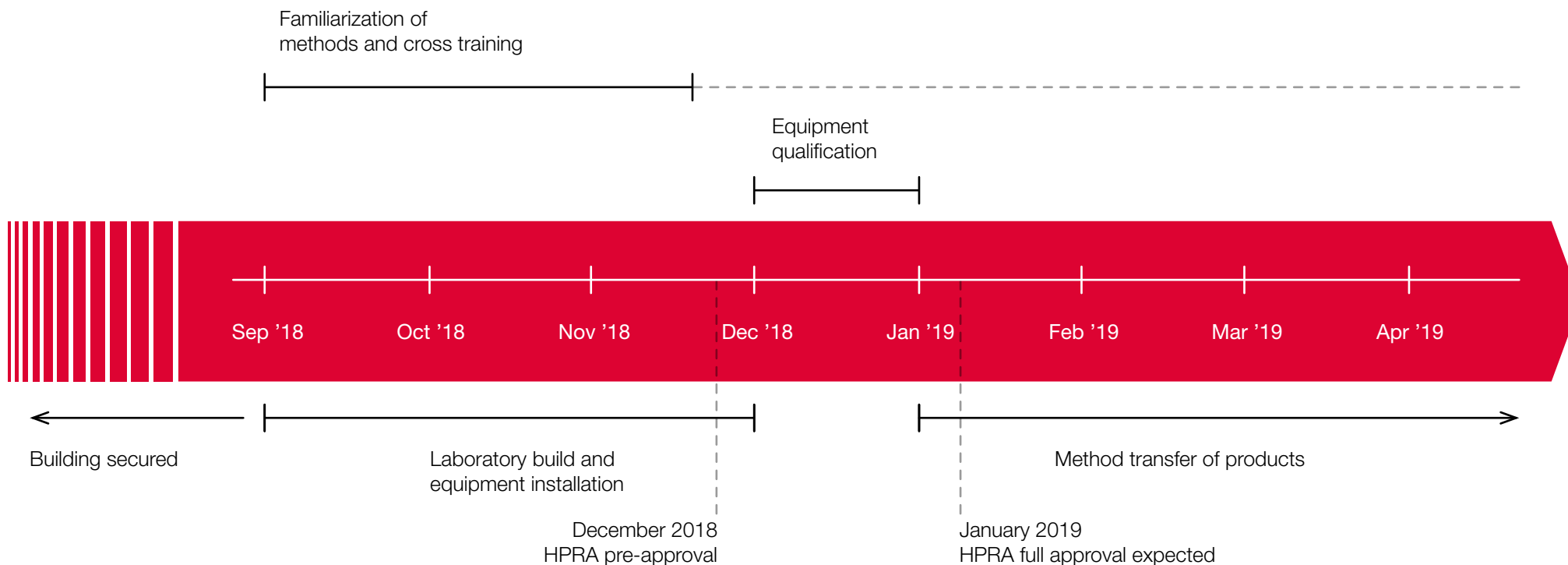
- A warehouse expansion project to increase storage capacity;
- A full EU QP releasing group;
- A full analytical laboratory, the timeline for which can be seen overleaf.

Whilst there are still unknowns regarding the UK and EU trading negotiations at the present time, PCI would like to assure you that we are working to ensure a seamless transition and continuity of supply for both existing and new customers.

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# PCI Pharma Services Ireland Laboratory Project Plan



## KEY MILESTONES

- December 2018 – HPRA pre-approval expected
- December 2018 – Equipment qualification
- January 2019 – HPRA approval expected
- January 2019 – First wave of method transfer