Brexit Regulatory Risk Mitigation – EU Clinical Trial Applications (CTAs)

FACT SHEET

Biotec Services Int Ltd
(trading as:
PCI Pharma Services)
Central Park, Bridgend Industrial Estate, Bridgend
CF31 3TY UK
Licence: MHRA MIA IMP Licence No. 19819
Click here:
GMP Certificate

Penn Pharma Services Ltd
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PCI Pharma Services)
Units 23-24, Tafarnaubach Industrial Estate, Tafarnaubach, Tredegar
NP22 3AA UK
Licence: MHRA MIA IMP Licence No. 4351
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GMP Certificate

AndersonBrecon UK Ltd
(trading as:
PCI Pharma Services)
Units 2-7, Wye Valley Business Park, Brecon Road, Hay-On-Wye, Hereford, HR3 5PG UK
Licence: MHRA MIA IMP Licence No. 11724
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GMP Certificate

PCI Europe – Clinical S&D

Millmount Healthcare Ltd
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Block 7, City North Business Campus, Stamullen, Co. Meath K32 YD60 Ireland
Licence: HPRA MIA IMP Licence No. 11566
Click here: **GMP Certificate**

Points to Note

- PCI QPs will review the IMPD on a protocol by protocol basis to determine how, if at all, any PCI UK sites need to be named on the PCI Ireland QP Declarations generated.
- Import Testing – There is no mandatory requirement to perform EU importation testing for IMPs.

New EU CTA filing(s) planned

List both PCI UK & PCI Ireland facilities as responsible for EU batch release in EU CTA section D.9.

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PCI will provide 2x QP Declarations from each facility to include in CTA submissions.

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GMP Certificates, if required, can be accessed via weblinks provided.

Submitted and/or Approved EU CTAs

If the CTA(s) filed only list PCI Bridgend UK (or PCI's other UK facilities at Hay and Tredegar) facilities as responsible for EU batch release in CTA section D.9, substantial amendments should be prepared and filed to also include PCI's Ireland facility as an *ALTERNATIVE* site of EU batch release.

Substantial amendment EU CTAs

Plan to list PCI Ireland as an *ALTERNATIVE* site of EU batch release, substantial amendments must be raised on a country by country basis.

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Name the PCI Ireland site alongside PCI UK site(s) as responsible for EU batch release.

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PCI will provide a QP Declaration signed by an Ireland QP named on PCI's Ireland MIA IMP licence as part of the amendment to be filed.

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Submit to each country and await approval.

Any questions, please contact Brexit@pciservices.com