Brexit Regulatory Risk Mitigation – EU Commercial Activities

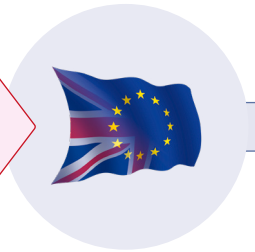
FACT SHEET

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

Penn Pharma Services Ltd
(trading as:
PCI Pharma Services)
Units 23-24, Tafarnaubach Industrial Estate, Tafarnaubach, Tredegar
NP22 3AA UK
Licence: MHRA MIA Licence No. 4351
Click here:
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 Licence No. 11724
Click here:
GMP Certificate

PCI Europe



Millmount Healthcare Ltd
(trading as: PCI Pharma Services)
Block 7, City North Business Campus, Stamullen, Co. Meath K32 YD60 Ireland
Licence: HPRA MIA Licence No. M00767
Click here: **GMP Certificate**

QP Declarations

PCI Europe QP team will generate QP Declarations as required to satisfy variation/filing applications so as to support ongoing QP certification services from PCI Pharma Services, Ireland entity (Millmount Healthcare).

New EU Filing to add Millmount Healthcare as site of QP certification

List both PCI UK and PCI Pharma Services, Ireland facilities as responsible for EU batch certification.

•••

PCI will provide 2x QP Declarations from each facility to include in filing (or as needed).

•••

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

Filed or Approved EU Release sites

If the current filing for the product lists any PCI UK site (Biotec, Penn, AndersonBrecon) as site of release or finished product Quality Control (QC) testing, variations should be prepared to vary licence to include PCI Pharma Services, Ireland (Millmount Healthcare) as an *ALTERNATIVE* site of EU batch release and QC testing.

Addition of PCI Pharma Services, Ireland to filing as site of release

Plan to list PCI Pharma Services, Ireland as an *ALTERNATIVE* site of EU batch release and QC testing, a variation to licence should be prepared.

•••

Name the PCI Pharma Services, Ireland site alongside PCI UK site(s) as responsible for EU batch release and QC testing.

•••

Liaise with PCI Pharma Services, Ireland to create a supporting Quality Technical Agreement (QTA) along with plan for on-boarding product for testing and release. Put in place plan to manage logistical matters, audit(s) and QP declarations as required.

Any questions, please contact Brexit@pciservices.com