IMPORTANT CHANGES TO eCTD & USE OF CESP

Are you ready?

TO DO...

2018 Q4: Optional use of CESP dataset module for human and vet new MAA application forms – mandatory in 2019/Q2

1st Jan 2019: Use of eCTD for all regulatory activities in national procedures - variations, renewals etc.

2019/Q1: Use VNeeS for all submissions in national procedures

2019/Q3: Mandatory use of the CESP portal for delivery of MRP/DCP submissions

2020/Q1: Optional use of CESP dataset module for variation and renewal application forms – mandatory in 2020/Q3

2020/Q3: Optional use of eCTD v4.0 in CP (human)

2021/Q3:

- Optional use of eCTD v4.0 in MRP/DCP (human)
- Preparation for the mandatory use of the integrated application form and submission for all submissions through a Single Submission Portal

LET DIAMOND TAKE CARE OF YOUR TO DO LIST

Diamond Pharma Services comprises three divisions that provide cutting-edge technical and operational services to the biotech and pharmaceutical industries through its experienced panel of employees and fully validated eCTD publishing software.

- Regulatory (Regulatory Affairs and Product Development)
- Pharmacovigilance (Pharmacovigilance & QPPV)
- Compliance & Quality (GLP, GMP, GCP and QP Services)

Diamond Pharma Services welcomes you to contact us for a confidential discussion on the support we can offer to take your company forward.

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