YOURWAY
THE BIOPHARMA SERVICES COMPANY

**Yourway Transport Ltd**
Unit 27, Contrail House,
Cedar Drive,
Dublin Airport Logistic Park,
Saint Margaret's,
K67 F8Y4, Ireland

28 February 2024

**IMP13154/00001**

**To Whom it may Concern**

**Catalent Pharma Solutions LLC**
1100 Enterprise drive,
Winchester,
KY 40391,
USA

Based upon an audit performed on 18th, 19th April 2023 I can confirm that the audit was completed satisfactorily, and observations noted during the audit have been addressed.

The facilities were audited against Compliance to current Good Manufacturing Practices in accordance with EU Directives 2003/94/EC, 2004/27/EC, and Eudralex 4 and FDA 21 CFR 210 and 211.

Catalent Pharma Solutions is registered with the FDA as a manufacturer of Non generic human prescription drugs.
The audit covered the facilities, Quality Control Laboratories. Manufacturing Areas, environmental controls and the QMS system.

The processes involved in the operation of the Catalent Winchester facility are manufacturing of solid dosage forms, Quality Control testing, and primary packaging, of clinical trial material.

All activities reviewed during the audit were covered by relevant SOPs and Work Instructions.

Training records reviewed confirmed that all relevant training had been completed.

It was noted during the tour that the facilities in the manufacturing areas, equipment, and quality control laboratory were well maintained, and all calibrations were in date.

I can confirm that the facility operates to EU GMP standards.

[redacted]

EVP Quality
EU/UK QP

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| Sr. No. | Site | Activity |
|---|---|---|
| 1 | Quotient Sciences – Philadelphia, LLC (formerly QS Pharma LLC)<br>3 Chelsea Parkway, Suite 305<br>Boothwyn, PA 19061, USA<br>FDA Establishment Identifier (FEI): 3003882011 | Manufacturing , primary packaging, Testing |
| 2 | Quotient Sciences – Philadelphia, LLC<br>3080 McCann Farm Dr<br>Garnet Valley, PA 19060, USA<br>FDA Establishment Identifier (FEI): 3014679374 | Testing |

Based upon an audit performed on March 22nd - 23rd, 2023 I can confirm that the audit was completed satisfactorily, and observations noted during the audit have been addressed.

The facilities were audited against Compliance to current Good Manufacturing Practices in accordance with EU Directives 2003/94/EC, 2004/27/EC, and Eudralex 4 and FDA 21 CFR 210 and 211.

Quotient Sciences Solutions is registered with the FDA as a manufacturer.
The audit covered the facilities, Quality laboratories. Manufacturing Areas, environmental controls and the QMS system.

The processes involved in the operation of the Quotient Sciences facility, are manufacturing of solid dosage forms, Quality Control testing, and primary packaging, of clinical trial material.

All activities reviewed during the audit were covered by relevant SOPs and work instructions.

Training records reviewed confirmed that all relevant training had been completed.

It was noted during the tour that the facilities in the manufacturing and quality control laboratory were well maintained, and all calibrations were in date.

I can confirm that the facility operates to EU GMP standards.

[redacted]

EVP Quality
EU/UK QP