viapath

Viapath
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*Sent on behalf of the Joint North London & South Thames Transfusion Science TAG*

Novo Nordisk

**Wednesday, 19 November 2014**

## *Contact & Quality Management Information*

Dear Sir/Madam,

I am writing to you to ensure that we have up to date contact details for your company and to fulfil our requirements of a supplier audit as part of the Good Manufacturing Practice guidelines.

I would be grateful, therefore, if you could complete this quality questionnaire, or pass it on to the person in your company best able to provide the information.

Please feel free to provide any extra information that may be pertinent, even if this has not been specifically requested.

With your permission, the responses to this questionnaire will be published on the London & SE Coast RTC website and will be used by hospitals nationwide to ensure their compliance with supplier auditing.

Please indicate if you do not want your responses to be published this way.

Please return the form to the address above either in electronic or paper format with a copy of any relevant accreditation certificates. Alternatively, please indicate where this can be found if available online.

Respectfully yours,

Barbara Umlauft

Viapath |Quality Officer
Blood Transfusion Laboratory
King's College Hospital

# ORGANISATION NAME AND ADDRESS

| | |
|---|---|
| Company Name: | **Novo Nordisk** |
| Company Address: | *3 City Place, Beehive Ring Road, Gatwick, West Sussex RH6 0PA* |
| Contact Name: | *Erica Burke* |
| Email: | *ebu@novonordisk.com* |
| Telephone: | *01293 762091* |
| Fax: | *01293 512581* |

**Please note NovoSeven orders should be sent to UDG, the distributor of NovoSeven and NOT to manufacturer**

# PRODUCT OR SERVICE DETAILS

| | |
|---|---|
| Product/Service Details: | *Plasma Products* |
| Model/ Item Number: | *NovoSeven* |

# SUPPLIER AUDIT QUESTIONNAIRE

| QUESTION | YES | NO |
|---|---|---|
| Do you currently hold any Quality Accreditation?<br>**We hold no official quality accreditation but are regularly audited by :horities including FDA, Danish regulatory authorities for our manufacturing ant in Denmark. Within the UK our quality systems were audited by MHRA from a GDP perspective.**<br><br>Please detail:<br>Inspection Body:<br>Accreditation Number/Reference:<br><br>Date of last/next inspection:<br><br>Outcome: Successful / Unsuccessful / Conditional / Not applicable | ☐ | X |
| **1. Quality Policy**<br>Is there a quality policy in place? | X | ☐ |
| **2. Organisation**<br>Are all responsibilities clearly defined? | X | ☐ |
| **3. Training**<br>Are there systems in place for training? | X | ☐ |
| Are staff appropriately qualified and trained to carry out procedures correctly? | X | ☐ |
| **4. Internal Quality Audits**<br>Are there procedures in place for planned quality audits? | X | ☐ |
| Is there a review of the effectiveness of your governance systems to ensure integrity and traceability? | X | ☐ |
| **5. Purchasing**<br>Is there a procedure in place for the control/assessment of suppliers, including verification of supplier's/manufacturers bona-fides? | X | ☐ |
| Does this procedure define actions to be taken when dealing with suppliers that do not meet the requirements? **We only buy from Novo Nordisk factories so not relevant** | ☐ | X |
| **6. Process Control**<br>Are there documented procedures for the processes? | X | ☐ |

| QUESTION | YES | NO |
|---|---|---|
| Are there any process / quality controls? | X | ☐ |
| Is there a formal release process? | X | ☐ |
| Is there a unique batch documented for each batch? | X | ☐ |
| Are certificates of analysis available? **We have certificates of analysis but they are considered commercially sensitive and therefore are not supplied. Certificates of Conformance would be available on request.** | ☐ | X |
| Have critical steps of the processes/premises and production and any significant changes been validated? | X | ☐ |
| Are records of manufacture including distribution retained in a comprehensible and accessible form? | X | ☐ |
| **7. Process Change Control** | | |
| Is there a documented procedure in place for change control to processing and materials used? | X | ☐ |
| Are there procedures for the investigation of non-conformances and documentation of corrective actions? | X | ☐ |
| **8. Recall** | | |
| Is there a procedure for the recall of a product? | X | ☐ |
| Is the effectiveness of the recall system regularly tested? | X | ☐ |
| Are complaints about products examined, the causes of quality defects investigated and appropriate measures taken in respect of the defective product and to prevent reoccurrence? | X | ☐ |
| **9. Handling, Storage and Delivery of the product** | | |
| Are these stages controlled to maintain product quality? | X | ☐ |
| Is the temperature monitored during transport? **The answer to this is normally yes – if it is not "monitored" during transport it would be sent out in validated packaging suitable for the journey.** If Yes, how/when is this reviewed and how are OTC events actioned? (*detail below*) | X | ☐ |

| QUESTION | YES | NO |
|---|---|---|
| | | |
| **10. Do we have your permission to share this questionnaire with the Joint TAG on the London & SE Coast RTC website?** http://www.transfusionguidelines.org.uk/ | X | ☐ |

| Additional Comments |
|---|
| *Please provide an explanation or brief description to any answers that were marked "NO"*: Market in gainst the questions above. |

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|---|---|
| Questionnaire completed by: ERICA BURKE | |
| Position: COMMERCIAL & LOGISTICS MANAGER | Date: 11 DEC 2014. |