

REGULATION AND PREQUALIFICATION DEPARTMENT

VACCINES ASSESSMENT TEAM

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LABORATORY RE-ACCREDITATION CHECKLIST

| | Doc No: IMD/TP/08b | Version No: 2 | Revise before: 30 Sept 2027 |
|--|-----------------------------------|---------------------------|-----------------------------|
| | Effective date: 30 Sept 2024 | Replaces: Annex 2 | Page 1 of 1 |
| | Approved by: | TL-VAX, date: 16 Sep 2024 | UH-PQT, date: 17 Sep 2024 |
| | on the day of printing or copying | | |

Laboratory re-accreditation checklist

Please verify that the following items and information are included with your email response. Please complete this checklist and include it in your reply.

All information will be treated in confidence.

| Item | Check | | |
|---|-------|--|--|
| Laboratory name | | | |
| Laboratory address | | | |
| Laboratory email address for general inquiries | | | |
| Laboratory phone number for general inquiries | | | |
| Best two contact persons for PQS work | | | |
| Contact person # 1 email address | | | |
| Contact person # 1 phone number | | | |
| Contact person # 2 email address or general "info address" | | | |
| Contact person # 2 phone number or general contact number | | | |
| Laboratory web page pdf with up-to-date details | | | |
| Copy of IEC 17025 Certificate | | | |
| Notarised copy of IEC 17025 Certificate in English, if necessary | | | |
| Copies of all other certificates (in English) | | | |
| CVs of key personnel | | | |
| Up-to-date copy of your laboratory's Quality Manual | | | |
| Current E00 categories, with proposed amendments if applicable | | | |
| Up-to-date copies of SOPs, TWI or similar | | | |
| A list of PQS testing carried out with dates and manufacturer / suppliers (See next page) | | | |