Risk Metrics form

1. Site Risk Category

High-risk products and processes include:

- sterile medicines, including biotechnology active pharmaceutical ingredients (APIs)
- non-sterile medicines containing antibiotics, steroids or antineoplastics
- tissue banks with complex processing
- cellular therapies

Medium-risk products and processes include:

- non-sterile medicines, including herbal, unless specified as high risk
- tissue banks with low manipulation

Low-risk products and processes include:

- homoeopathic medicines
- minerals, vitamins, fish oils and other supplements
- medicinal gases
- labelling/packaging; analysis/testing; Storage

2. Outcome of GMP report classification

A1 **Good compliance**
(Deficiencies or non-conformities were found, which are of a relatively minor nature and/or less than 3 major deficiencies)
A2 **Satisfactory compliance**
(3-10 major deficiencies)
A3 (warning letter) **Basic compliance**
(A large number of major (more than 10) and/or few critical deficiencies not need to suspend and/or revoke
Registration suspend **Bad compliance**
("critical" deficiencies, management decision not need to revoke)
Registration revoke **Highly risk compliance**
("critical" deficiencies, management decision which need to revoke)

3. Matrix table

Risk category	A1 category	A2 category	A3 category (warning letter)
	Frequency of re-audit (months)		
High	24	12	6
Medium	30	24	9
Low	36	30	12

4. Outcome result (Risk score): ……..
5. Done by: ……
6. Approved by: ……

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