



Technical Note on QUAMED GSDP and GMP classifications - July 2022

QUAMED will **introduce GSDP/GMP levels** in all QUAMED reports and database from July 2022 onwards. The objective is to allow a comparison between suppliers that have been assessed using different assessment techniques (technical visits or audits). QUAMED's Technical Committee has determined that this is currently the best way to compare suppliers in regard to their compliance with WHO GSDP, MQAS and WHO GMP standards.

These classification tools are already used for the conclusion of a Local Market Assessment (LMA), and they will now be extended to all future audit and technical visit reports. The QUAMED database will reflect this change in the near future.

Both the GSDP and the GMP classifications have 4 color-coded levels, and they include references to WHO-listed authorities (WLA) of maturity levels 3 and 4 (see below).

QUAMED recommends purchasing from suppliers with a GSDP level of 2 or higher, and sources with a GMP level of 3 or higher.

GSDP Levels	
Level 4	<ul style="list-style-type: none"> GSDP / GDP approved distribution sites by an SRA, or by a WLA ML4 GSDP / GDP inspections should have been conducted not more than 3 years ago, unless otherwise justified.
Level 3	<ul style="list-style-type: none"> Distribution sites having successfully passed a QUAMED GSDP or MQAS audit by QUAMED, or Distribution sites GSDP/GDP approved by an organization officially recognized by QUAMED, or GSDP/GDP approved distribution sites by a WLA ML3, GSDP / GDP audits/inspections should have been conducted not more than 3 years ago, unless otherwise justified.
Level 2	<ul style="list-style-type: none"> Distribution sites with an acceptable level of GSDP compliance (Global GSDP compliance $\geq 60\%$) during a GSDP technical visit or a remote GSDP technical visit by QUAMED, or Distribution sites with an acceptable level of GSP compliance <u>with restrictions</u>, after a GSDP or MQAS audit by QUAMED and/or other official or recognised organisations. GSDP/GDP audits/technical visits must have been performed within the last 3 years, unless otherwise justified.
Level 1	<ul style="list-style-type: none"> Distribution sites that had an unsatisfactory level of GSDP compliance with the GSDP requirements (Global GSDP compliance $< 60\%$) during a GSDP technical visit by QUAMED. GSDP/GDP audits/technical visits must have been performed within the last 3 years, unless otherwise justified.

GMP Levels	
Level 4	<ul style="list-style-type: none"> Manufacturing sites approved by a SRA or by a WLA ML4, or by WHO-PQ GMP inspections should have been conducted not more than 3 years ago, unless otherwise justified.
Level 3	<ul style="list-style-type: none"> Manufacturing sites having successfully passed a QUAMED GMP audit; or Manufacturing sites GMP approved by another organization officially recognized by QUAMED; or Manufacturing sites GMP approved by a WLA ML 3 <p>GMP audits/inspections should have been conducted not more than 3 years ago, unless otherwise justified.</p>
Level 2	<ul style="list-style-type: none"> Manufacturing sites with an acceptable level of GMP compliance <u>with restrictions</u>, after an audit by QUAMED and/or other official or recognised organisations <p>GMP audits should have been conducted not more than 3 years ago, unless otherwise justified.</p>
Level 1	<ul style="list-style-type: none"> Manufacturing sites with proven unsatisfactory GMP compliance level, whatever the source of info (audits carried out by QUAMED and/or other official or recognised organisations). <p>GMP audits should have been conducted not more than 3 years ago, unless otherwise justified.</p>
Level unknown	<ul style="list-style-type: none"> Manufacturing site with no GMP information or decision pending or obsolete info.



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