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Ref. No.:- F.02(57)/RMSCL/Proc./S&S(MD)/NIB-5/2018/ 296

Dated: 24/07/2018

**Corrigendum – 3**

**Subject:- Amendments in bid conditions**

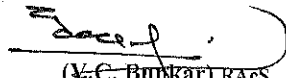
**Ref.:- Pre bid meeting dated 28.06.2018 and NIB No. F.02(57)/RMSCL/Proc./S&S(MD)/NIB-5/2018/269 Dated:20.06.2018**

S. No	Existing condition	Amended condition
1	<p><b>Clause 5(l) Technical Bid</b>                      (l) For Importer, WHO-GMP/COPP/FDA certificate of the exporting country should be submitted. For manufacturer, Quality Management System (QMS) Certificate as per Schedule V of Medical device Rules 2017 should be submitted. The QMS certificate must not be older than one year from the due date of Bid submission in the case where validity is not mentioned in the certificate. The QMS certificate of all the manufacturing plants, of which products have been quoted, should be submitted. The Bidder shall also furnish an undertaking in the format given in Annexure-VII point no.9 declaring that the Bidder complies with the requirements of QMS (as per Medical Device rules 2017). The Importer should produce WHO- GMP /COPP/FDA of the manufacturing firm or a certificate which is at par with WHO-GMP issued by exporting countries like US- FDA approval, etc. In the case of imported surgical and sutures drugs items, labels and product literature of all quoted products must be submitted. The Firm will continue to hold WHO-GMP/COPP/QMS Certificate for the product during entire rate contract period of the product. If WHO-GMP/COPP/QMS certificate expires, it is firm's responsibility to inform RMSCL about the same and not to accept any further purchase order till re-issue /renewal of WHO-GMP/COPP/QMS certificate. During the period of non validity of WHO-GMP/COPP/QMS certificate of the firm the rate contract will deemed to be suspended. If the firm fails to inform RMSCL about the expiry of WHO-GMP/COPP/QMS certificate and accept purchase order of RMSCL and later on it comes to the knowledge of RMSCL, such product of the firm shall be liable to be debarred for a period of two years from the date of order.                      NOTE:- In case of manufacturer/loan license if firm is not having QMS certificate, GMP certificate issued before 1 Jan 2018 will be acceptable, if valid on bid opening date. The WHO-GMP/GMP/COPP/QMS certificate must not be older than one year from the last date of Bid submission in case validity is not mentioned in the certificate.</p>	<p><b>Clause 5(l) Technical Bid</b>                      (l) For Importer, WHO-GMP/COPP/FDA certificate of the exporting country should be submitted. <b>For manufacturer, Quality Management System (QMS) Certificate as per Schedule V of Medical device Rules 2017/ GMP as per revised Schedule –'M', should be submitted. The QMS/ GMP certificate must not be older than one year from the due date of Bid submission in the case where validity is not mentioned in the certificate. The QMS/GMP certificate of all the manufacturing plants, of which products have been quoted, should be submitted. The Bidder shall also furnish an undertaking in the format given in Annexure-VII point no.9 declaring that the Bidder complies with the requirements of QMS (as per Medical Device rules 2017)/ GMP. The Importer should produce WHO- GMP /COPP/FDA of the manufacturing firm or a certificate which is at par with WHO-GMP issued by exporting countries like US- FDA approval, etc. In the case of imported surgical and sutures drugs items, labels and product literature of all quoted products must be submitted.</b>  <b>The Firm will continue to hold WHO-GMP/COPP/QMS/ GMP Certificate for the product during entire rate contract period of the product. If WHO-GMP/COPP/QMS/ GMP certificate expires, it is firm's responsibility to inform RMSCL about the same and not to accept any further purchase order till re-issue /renewal of WHO-GMP/COPP/QMS/ GMP certificate. During the period of non validity of WHO-GMP/COPP/QMS/GMP certificate of the firm the rate contract will deemed to be suspended. If the firm fails to inform RMSCL about the expiry of WHO-GMP/COPP/QMS/GMP certificate and accept purchase order of RMSCL and later on it comes to the knowledge of RMSCL, such product of the firm shall be liable to be debarred for a period of two years from the date of order.</b></p>



		NOTE:- The WHO-GMP/GMP/COPP/QMS certificate must not be older than one year from the last date of Bid submission in case validity is not mentioned in the certificate.
2	<p><b>Annexure VII (Point 9)</b> That we have approved qualified staff, machines &amp; equipments along with capacity to manufacture above category of Surgical &amp; Sutures and our unit have been issued WHO-GMP/COPP/ QMS* by Concerned Competent Authority vide letter No.....dated.....valid up to.....</p> <p>* In case if firm is not having QMS certificate, GMP certificate issued before 1 Jan 2018 will be acceptable, if valid on bid opening date. The WHO-GMP/GMP/COPP/QMS certificate must not be older than one year from the last date of Bid submission in case validity is not mentioned in the certificate.</p>	<p><b>Annexure VII (Point 9)</b> That we have approved qualified staff, machines &amp; equipments along with capacity to manufacture above category of Surgical &amp; Sutures and our unit have been issued WHO-GMP/COPP/ QMS/GMP* by Concerned Competent Authority vide letter No.....dated.....valid up to.....</p> <p>* The WHO-GMP/GMP/COPP/QMS certificate must not be older than one year from the last date of Bid submission in case, validity is not mentioned in the certificate.</p>

- Rest terms and conditions will remain the same.

  
 (V.C. Bunkar) RACS  
 Executive Director (Proc.)  
 RMSC