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ASIA EDITION

Austrianova facility commissionedÃ?Â forÃ?Â GMP manufacturing

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SINGAPORE: AustrianovaÃ?Â announced that its facility in Bangkok, Thailand has been externally assessed as beingÃ?Â ready toÃ?Â manufactureÃ?Â biologic products under currentÃ?Â Good Manufacturing Practice (GMP).TheÃ?Â assessment wasÃ?Â issued by ChamowÃ?Â &Ã?Â Associates,Ã?Â a U.S.Ã?Â basedÃ?Â expert biopharmaceuticalÃ?Â consultingÃ?Â compay that specializesÃ?Â in inspection ofÃ?Â facilitiesÃ?Â forÃ?Â GMPÃ?Â compliance, working onÃ?Â behalf of Austrianova's partner PharmaCyteÃ?Â Biotech Inc.

The assessment processÃ?Â was initiatedÃ?Â with a site visit and audit of Austrianova's facility in Bangkok, Thailand at the end of last year, followed by a comprehensive
evaluation of key documents such as the quality management system manual and numerous key facility related standard operating procedures (SOPs)for compliance with USFDA requirements forÃ?Â GMP pharmaceutical production facilities.

The assessment process also included validation that all facility related equipmentÃ?Â has completed the Installation Qualifications(IQ) and Operational Qualifications (OQ).

Earlier this year, AustrianovaÃ?Â beganÃ?Â offeringÃ?Â newÃ?Â cellÃ?Â bankingÃ?Â and filling Ã?Â services called GMP4CellsÃ?Â thatÃ?Â includesÃ?Â MasterÃ?Â CellÃ?Â Bank (MCB)Ã?Â andÃ?Â WorkingÃ?Â CellÃ?Â Bank (WCB) productionÃ?Â asÃ?Â wellÃ?Â asÃ?Â a "FillÃ?Â andÃ?Â Finish" Ã?Â service Ã?Â for Ã?Â cell Ã?Â therapy Ã?Â products

(e.g.stemÃ?Â cell therapiesÃ?Â asÃ?Â wellÃ?Â asÃ?Â biologicsÃ?Â producedÃ?Â fromÃ?Â cellsÃ?Â suchÃ?Â as vaccines, antibodies, recombinantÃ?Â proteinsÃ?Â etc).

GMP4Cells isÃ?Â providedÃ?Â inÃ?Â additionÃ?Â toÃ?Â Austrianova'sÃ?Â moreÃ?Â well establishedÃ?Â Cell-inÃ?Â¢Ã¢â??Â¬Ã?Â•a-BoxÃ?Â cellÃ?Â encapsulationÃ?Â services."We are Ã?Â pleased Ã?Â to Ã?Â reach Ã?Â this Ã?Â important Ã?Â milestone forÃ?Â ourÃ?Â GMPÃ?Â facility,Ã?Â whichÃ?Â we believeÃ?Â toÃ?Â beÃ?Â theÃ?Â firstÃ?Â of itsÃ?Â kindÃ?Â worldwide", stated WalterÃ?Â H.Gunzburg, Chairman and CTO of Austrianova.
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