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for professionals in process and analytical methods development, manufacturing, quality systems, regulatory affairs, facility design, and contract services.

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Please include author details: affiliations, job titles, credentials (PhD, MD, MBA, etc.). Indicate the corresponding author(s) along with contact information (address, phone number, and email address).

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Submit illustrations, photos, and figures as separate, high-res digital files: EPS, PSD, TIFF, PDF, PNG, PPT, or JPG formats (~300 dpi). Authors will be contacted if improved resolution is required. For tables, we prefer working with text rather than images for greater layout flexibility and enhanced readability. Figures and tables should be sequentially numbered

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### REFERENCE FORMATTING

Throughout the paper, and at the end of the article, provide the references in numerical order. Formatting examples are shown below. Provide the DOI and PubMed ID information when available. Unless a reference has been accepted for publication, it must be designated as "Unpublished."

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After layout, the corresponding author will be emailed an article proof (in PDF format) to review for accuracy. Production staff will incorporate the author's designated corrections/revisions, obtain final approval, and then the completed article will be posted to our website where readers can download the article at no cost.

Authors will be emailed the article citation and a high-resolution PDF file for their open access use (self-archiving, sharing electronically, and reproduction).

#### Magazine or Journal Articles:

[1] Hahn TJ *et al.* Rapid manufacture and release of a GMP batch of avian influenza A(H7N9) virus-like particle vaccine made using recombinant baculovirus-Sf9 insect cell culture technology. *BioProcess J*, 2013; 12 (2): 4-17. <http://dx.doi.org/10.12665/J122.Hahn>

[2] Sarwar UN *et al.* Safety and immunogenicity of DNA vaccines encoding Ebolavirus and Marburgvirus wild-type glycoproteins in a phase I clinical trial. *J Infect Dis*, 2014. Epub ahead of print. <http://dx.doi.org/10.1093/infdis/jiu511> PMID 5225676

#### Press Releases:

[3] J. Craig Venter Institute. (2013). Prepared statement from J. Craig Venter, PhD, and the J. Craig Venter Institute and Synthetic Genomics Vaccines, Inc. on the H7N9 avian flu strain in China [Press release]. Retrieved from [http://www.jcvi.org/cms/press/press-releases/full-text/article/prepared-statement-from-j-craig-venter-phd-and-the-](http://www.jcvi.org/cms/press/press-releases/full-text/article/prepared-statement-from-j-craig-venter-phd-and-the-j-craig-venter-institute-and-synthetic-geno/)

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#### Regulatory:

[4] FDA (CDER/CBER/CVM) Guidance for Industry. *Process validation: general principles and practices*. Jan. 2011, CGMP, Rev. 1. <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM070336.pdf> (Accessed 24 March 2015)

[11] International Conference on Harmonization. ICH Topics Q5A – Notes for guidance on quality of biotechnological products: *Viral safety evaluation of biotechnology products derived from cell lines of human or animal origin. Step 4 consensus guideline*. 4 March 1997 (CPMP/ICH/295/95).

[12] *Cell cultures for veterinary vaccines*. European Pharmacopoeia, 4th ed. General chapter 5.2.4; 2002.

#### Books:

[18] Sambrook J. *Molecular cloning: a laboratory manual*, 2nd ed. New York: Cold Spring Harbor Laboratory; 1989.

[21] Kozak CA, Ruscetti S. Retroviruses in rodents. In: Levy JA, editor. *The Retroviridae, Vol. 1*. New York: Plenum Press; 1992. p 405-430.

#### Patents:

[18] Blom WR, Kunst A, van Schie BJ, Luli GW, inventors; Quest International Flavors & Food Ingredients Company, assignee. *Method for in vitro growth of eukaryotic cells using low molecular weight peptides*. US patent 5,741,705. 1995 Feb 23.

#### Oral and Poster Presentations:

[22] Petry H *et al.* *Hurdles faced from the quality perspective during the Glybera® approval process*. Presented at the ISBioTech 3rd Annual Meeting; 2013 March 11-15; Rosslyn, Virginia USA.

[23] Vasilyeva E *et al.* *Development of a chip-based electrophoresis method for the determination of half-antibody molecules in IgG4*. Poster presented at the 2002 WCBP Conference; 2002 January 21-27; San Francisco, California USA.