



Figure 6.6 Multilevel Ishikawa diagram depicting the connection between process parameters, COAs, and targeted quality profile. A data set of a selected QTPP specification (glycosylation pattern) and a selected CQA (galactosylation) is shown as an example. Dashed lines represent the logical linkage between consecutive stages of process development, condensed in risk questions. (From Zalai, D. et al., *PDA J Pharm Sci Tech*, 67, 2013. With permission.)