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characterization of  
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properties), familiarity  
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of concerning  
formulation and  
analytical strategies  
from one area to

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Successful  
preformulation requires  
knowledge of  
fundamental molecular  
concepts (solubility,  
ionisation, partitioning,  
hygroscopicity and  
stability) and  
macroscopic properties  
(physical form, such as  
the crystalline and  
amorphous states,  
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In the second half of  
this two-part series,  
the author suggests  
that to qualify and  
validate a  
pharmaceutical  
manufacturing facility,  
one must coordinate  
protocol and SOP

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development, scheduling and implementation, turnover package preparation, and the management and resolution of deviations and discrepancies. In combination with the programs described in Part I, these activities will help ...

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