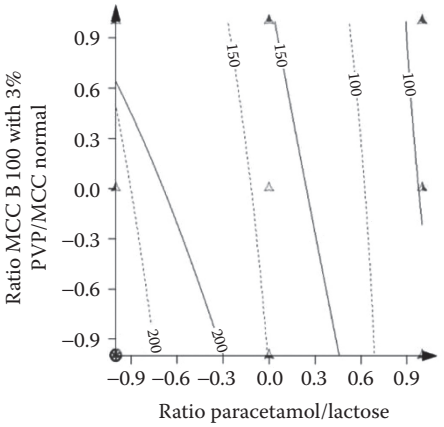

FIGURE 20.9 Effect of the tableting speed on a Paracetamol formulation as a function of the ratio *MCC B 100 granulated with 3% PVP/MCC normal and the ratio Paracetamol/lactose. (From Leuenberger, H., 9th Scientific and Technical Forum, Basel, Switzerland, 2013. www.ifiip.ch/downloads, conference materials.)

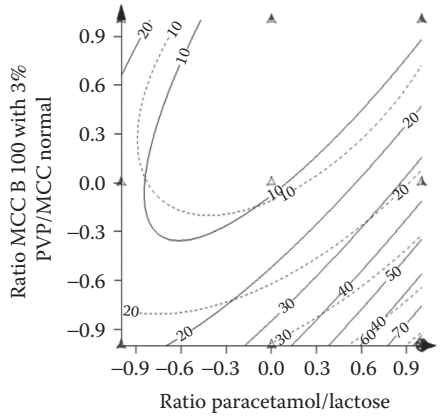

FIGURE 20.10 Tablet disintegration time in sec as a function of the composition (Figure 20.9) and as a function of the tableting speed (Figure 20.9). (From Leuenberger, H., 9th Scientific and Technical Forum, Basel, Switzerland, 2013.)

performed in the laboratory, such as mixing of API with excipient particles, granules growth, compaction of particles, granulates, and so on, and is able to test the API dissolution profile of the respective tablet formulation. Thus, significant financial savings can be realized by replacing expensive lab work with computer simulation. This approach facilitates the exploration of the formulation design space for preparing tablet samples for clinical phase I with a 6σ quality (Figure 20.11). In order to take full advantage of this approach a harmonization of the equipment and of the processes is needed (Leuenberger and Leuenberger, 2016).

Cellular Automaton (CA): A First Principle Approach

The CA approach mimics exactly what happens in reality. Thus, the *in-silico* results have a very high credibility, which is higher than any expert system based on in-house data obtained in the past with similar formulations. Owing to the possibility that the first *in-silico* results can be calibrated with a first lab tablet formulation—that is, performing a *fine-tuning* of the necessary *in-silico*