




GCP Problem Solving Workshop

Study Coordinator Training

Australia/New Zealand 2009



8.30 – 9.00	Arrival tea and coffee	
9.00 – 10.15	Trial regulations and quality	
10.15 – 10.30	Break	
10.30 – 12.00	Problem solving and decision making <ul style="list-style-type: none">– Identification of problems– Assessing the level of seriousness– Identifying causes and solutions– Selecting the most appropriate solution	
12.00 – 12.45	Lunch	
12.45 – 15.00	The key New Zealand regulatory guidance documents – what are the main points/key differences and dealing with common problems in applying the guidelines <ul style="list-style-type: none">– SCOTT approval– ICH GCP/NZ GCRP– Health Information Privacy Code– Ethics Guidance and Standards– Case studies	
15.00 – 15.15	Break	
15.15 – 16.45	Problem solving/problem prevention workshop	