

WORKSHOP

“REGULATORY ISSUES IN THE DEVELOPMENT OF BIOLOGICAL MEDICINAL PRODUCTS”



May 30, 2008

*Science and Technology Park of Sardinia “Sardegna Ricerche”
Pula (Cagliari), Sardinia, Italy*



**SARDEGNA
RICERCHE**



PROGRAM

- h 12.30 Welcome cocktail
- h 13.30 Opening Session: G. Murgia and F. Marcheschi (Sardegna Ricerche)
- Chairperson: G. Vicari
- h 14.00 “Assessment of Quality and Validation of Production and Analytical Methods” (C. Pini, ISS)
- h 14.30 “CTD of a therapeutic protein” (R. Schrepfer, Bio-Ker S.r.l.)
- h 15.00 “Pre-clinical Development: Overview of Different Aspects of Kinetics and Immunogenicity Measurement” (I. Andreini, RTC S.p.A.)
- h 15.30 Coffee Break
- h 16.00 “EMA Scientific Advice” (S. Vella, ISS)
- h 16.30 “Clinical Development” (Ursula Herranz, Cross Alliance)
- h 17.00 “Marketing Authorization Process” (P. Rossi)
- h 17.30 “Drug Development Process” (G. Dastoli/P.Galassi, Eudax S.r.l.)
- h 18.00 – 19.00 Round Table
- h. 21.00 Social Dinner

SCIENTIFIC COMMITTEE

G. Vicari; G. Tonon; A. Bulfone; F. Caboi; P. Onali

ORGANIZING SECRETARY

Vania La Francesca Email: vania.lafrancesca@bioflag.it

Telefono: +39 0709243.5145/5146 Fax: +39 070 9243.5142

REGISTRATION

<http://www.sardegna ricerche.it/agenda/eventi/>

Free registration

OFFICIAL LANGUAGE

English

AFFILIATED HOTEL

Rocca Dorada Village Club Resort ***** e-mail: roccadorada@alice.it

S.S.195 Km 41,200 Santa Margherita di Pula

Tel: 070/9290037- 070/9290240 Fax 070/9290150