

# PILOT SCALE DEMONSTRATION OF BIOMATERIAL FOR MEDICAL CARE

(INS/8/021) F5 New

MODEL PROJECT

## CORE FINANCING

YEAR	Experts		Group Activity	Equipment	Fellowships		Scientific Visits		Group Training	Sub-Contracts	Misc. Comp.	TOTAL
	m/d	US \$	US \$	US \$	m/d	US \$	m/d	US \$	US \$	US \$	US \$	US \$
1999	0/14	6,860	0	55,000	6/0	20,700	0/14	5,040	0	0	0	87,600
2000	0/14	7,210	0	70,000	12/0	43,200	0/0	0	0	0	0	120,410

First Year Approved: 1999

**OBJECTIVES:** To develop pilot scale production technology of hydrogel wound dressing for the future commercialization of the products by industry.

**BACKGROUND:** During the past five years, BATAN has successfully developed synthetic hydrogel wound dressing based on polyvinyl alcohol (PVA) and polyvinyl pyrrolidone (PVP). Although these products were designed specifically for the tropics, there are still problems to scale up the production process from laboratory through pilot to industrial scale, such as inhomogeneity of mixer solutions, a stickiness problem with packaging, and

formation of air bubbles in the product during irradiation. These problems will be addressed by this project, as their elimination will make investment more attractive to industry. A private company, interested in the technology and the products, is involved in the project, as is the relevant national regulatory authority, the Directorate General of Drug and Food Control, Ministry of Health, to streamline the licensing process.

**PROJECT PLAN:** During 1999, with the provision of Agency expert services on hydrogel manufacturing, equipment, and fellowship training, the radiation synthesis technology of biomaterials will be established. Pre-clinical tests and clinical tests of the products will be performed. In 2000, a pilot scale production line of biomaterials will be completed, followed by applications for clearance and approval by the health authorities, and technology transfer to private industry that has been involved in this project from the initial stage.

**NATIONAL COMMITMENT:** Laboratory with a gamma irradiator; a radiation processing facility; preclinical and clinical testing of hydrogel; staff and operation costs; involvement of end users and regulatory authority. The project will sustain itself through technology transfer to private industry.

**AGENCY INPUT:** Expert missions on hydrogel manufacturing and biomaterial evaluation, equipment related to pilot scale production of hydrogel, fellowships.

**PROJECT IMPACT:** The project will benefit the health sector by supplementing tissue banking activities. A private company interested in the commercialization of biomaterial is directly involved to ensure the technology transfer and economic impact of the project.