



PRIX GALIEN JAPAN



CHARTER OF THE PRIX GALIEN JAPAN COMMITTEE



The Prix Galien rewards excellence and novelty, and awards additional honors to those who show great promise in the fields of innovative therapeutics, and who have served humanity at large.

The pharmaceutical, biotechnology, orphan and rare disease, and medical technology entries considered for the Prix Galien Japan Award must be fully PMDA approved, and digital health entries must be fully authorised or certified for market use in Japan.

Provisional approvals are not sufficient for any category. Entries shall have been based on innovative science, developed by synthetic chemistry or molecular biology, manufactured to precise specifications, tested in controlled clinical trials managed by ethical pharmaceutical companies; where eligible, entries must have received marketing approval in Japan by December 31 of the year preceding the award, but not more than seven years earlier than December 31 of that year, unless the award is for a new and innovative indication, which must have been added within the previous seven years. In all categories, nominees are assumed to have obtained permission from the current owner(s) of the product rights.

The Committee will award the following prizes:

- the Best Pharmaceutical Product (i.e. small molecule),
 - the Best Biotechnology Product,
 - the Best Orphan and Rare Disease Product,
 - the Best Medical Technology Product,
 - the Best Digital Health Solution, and
- the Best Start-Up in the fields of Biotechnology, Medical Technology, or Digital Health.

As to the science, candidates will be chosen from among all therapeutic categories, and each will be judged against all of the others.

The prizes will be awarded for pharmaceutical science that improves the human condition, principally based on three criteria:

- I. What was innovative in the course of this product's scientific development, application or clinical utility?
- II. What was learned for the future of biomedical science from this product's introduction to the clinic?
- III. What impact has the product had on improving the human condition?

Criteria that will not be considered are the size of the market, the size of the company, the cost of development or the contingencies of distribution. The Committee has the right to not select a winner in a particular year. In addition, at the discretion of the Committee and the Board of the Galien Foundation, the Prix Galien Japan may award a special distinction, the Young Promising Doctors and Scientists of Japan Award, recognising early-career doctors and scientists in Japan whose originality, promise, and emerging achievements offer important insights for the future of biomedical science. The Committee may also award the Pro Bono Humanum Award on an individual, a company, an academic institution, or a non-governmental organisation that has helped to improve the human condition.

Other new awards, consistent with the mission of the Galien Foundation, are planned. At the discretion of the committee, these awards will be judged by the committee members.

The awards committee will be composed of up to ten individuals and an honorary member chosen by the Board of the Galien Foundation. Except at the onset, committee members will generally serve for one, or a maximum of two, three-year terms. Membership duration will be staggered. Members shall be highly distinguished individuals from the scientific and research communities, primarily from Japan.

In addition to outstanding academic credentials, committee members must have extensive experience in the uses and understanding of human therapeutics, and must be familiar with research. The Galien Board, in consultation with the committee, will choose a Chair. The Board will entertain nominations for the committee from current committee members, former committee members, the academic and research communities, and from the scientific divisions of companies engaged in the development of human therapeutics.

The decisions of the independent committee with respect to the choice of winners for awards will be final and upheld by the decision of the committee. The committee deliberations will be conducted in private, and without any input whatsoever from the Board of the Foundation, or from Member organizations or other sponsors.