



Original Article

Human resource development contributes to the creation of outstanding regenerative medicine products

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ABSTRACT

Regenerative medicine is currently the focus of global attention. Countries all around the world are actively working to create new regenerative treatment modalities through pioneering research and novel technologies. This is wonderful news for patients who could not be treated with existing medical options. New venture businesses and companies are being established in regenerative medicine and their rapid industrialization is anticipated. However, to ensure high-quality products, human resources qualified in research and development and the manufacturing of these products are essential. The Forum for Innovative Regenerative Medicine (FIRM) conducted a questionnaire of its industry members to examine the training and hiring of people in research and development, product creation, manufacturing, and more. Regenerative medicine is a brand new field; thus, many different businesses will need to cooperate together. People with a broad range of technical skills, abilities, and knowledge will be in demand, with various levels of expertise, from basic to advanced.

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1. Introduction

Ever since Yamanaka et al. discovered induced pluripotent stem (iPS) cells [1], regenerative medicine has advanced in leaps and bounds, with extensive progress in clinical research and studies in Japan and globally [2]. In Japan, two laws were established in November 2014 [3–6]. The Act on the Safety of Regenerative Medicine and The Act on Pharmaceuticals and Medical Devices (PMD Act) were implemented to ensure an infrastructure existed that was conducive to the development of innovative regenerative medicine products. The research and development, clinical research, clinical studies, and marketing of Japan's regenerative medicine products are currently drawing attention from around the globe [7]. In Japan, two products were newly available in 2015,

HeartSheet[®] and Temcell[®] [5,8], after JACE[®] and JACC[®], showing amazing progress in this field.

Regenerative medicine has revived hope in many patients who, until now, lacked viable therapy options other than highly-advanced treatments such as organ transplantation. These new technologies have the potential to offer alternative treatment modalities to these patients. Those who, until now, expected to require life-long treatment may now have alternative options, which will also offer medical economic benefits [5,9,10]. However, regenerative medicine itself still carries a high price-tag, which must be addressed [11]. In addition, the shortage of human resources is a barrier for the development of regenerative medicine.

Regenerative medicine is a rapidly developing field and its progress has come primarily from within academia and venture businesses where the necessary human talent had been nurtured on an individual basis. As industrialization progresses, however, many venture businesses and corporations will engage in product development and marketing, focusing attention on the need for human resource development. Industrial associations must identify the type and number of people that will be required in key positions. For future progress in the regenerative therapy industry, not

Abbreviations: FIRM, Forum for Innovative Regenerative Medicine; iPS, induced pluripotent stem; GMP, Good Manufacturing Practice; GCTP, Good Gene, Cellular, and Tissue-based Products Manufacturing Practice.

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only will we need to identify what sort of personnel will become necessary, but also how to train people and how to undertake initiatives to meet these needs.

The Forum for Innovative Regenerative Medicine (FIRM) is a federation of approximately 200 venture businesses and companies that work towards the industrial promotion of regenerative medicine [12]. The FIRM comprises not only highly-specialized venture businesses and companies, but also includes those that deal in pharmaceutical products and medical devices and want to enter this field; businesses in related fields such as those creating machines, devices, reagents, and media; those that distribute these products; health insurance companies that provide medical insurance; human resource companies; and other businesses in a diverse range of fields. All these institutions have joined our association because they are invested in the future development of regenerative medicine.

The FIRM will need to acknowledge the challenges facing these businesses and to clarify their ideals and the type of employees that they seek. Thus, we conducted a survey of all the corporate members to gather this information. As technology grows ever more sophisticated, employees in these fields are required to maintain cutting-edge technology and expertise in these specialties. The highly diverse industries that are part of FIRM revealed that regenerative medicine calls for cooperation among various companies with distinct specialties and each will require highly-specialized personnel. This survey was carefully constructed to gain a better understanding of the talent cultivation needed, the type of opportunities required to train these personnel, the needed certification programs, and the way to establish the training systems.

2. Methods

This questionnaire study was conducted, by the education board at FIRM, to survey the special need for human resources among the fields of regenerative medicine. This survey was conducted from November 2–16, 2015. A questionnaire was sent to all full members

and supporting members of FIRM, a total of 175 companies. The questionnaire consisted of 100 items relevant to (1) the background of the responder company, (2) plans for training personnel and hiring, (3) plans for a training program and method, (4) required human resources, and (5) the need for a certification and training system. All questions had some alternatives, and responders could select one or more (when indicated) options. Responders could also add comments with sentences for some questions. Questionnaire sheets were sent to the FIRM office by mail, and the answers were aggregated. The results were monitored and we received a quality certification by STATcom Co. LTD.

3. Results

3.1. Background

We received replies from 110 of the 175 companies, for a very high recovery rate of 63% that reflected the high level of interest among FIRM member companies in training personnel in this field. Companies that responded to the questionnaire were classified by scale. The largest companies with ≥5000 employees accounted for 31%, those with ≥300 accounted for 30%, small- to medium-sized businesses accounted for 28%, and ventures and miscellaneous businesses made up the remaining 15%; therefore, company sizes were evenly distributed. Industry types were analyzed based on company size and we found major corporations tended to be involved in peripheral industries such as machinery, devices, chemicals, and raw materials. As the company scale grew smaller, the more likely they were to be dealing directly in regenerative medicine, and companies focused on regenerative medicine were primarily venture businesses (Fig. 1).

3.2. Plans for personnel training and hiring

When participants were allowed multiple options regarding future personnel training and hiring plans for regenerative fields

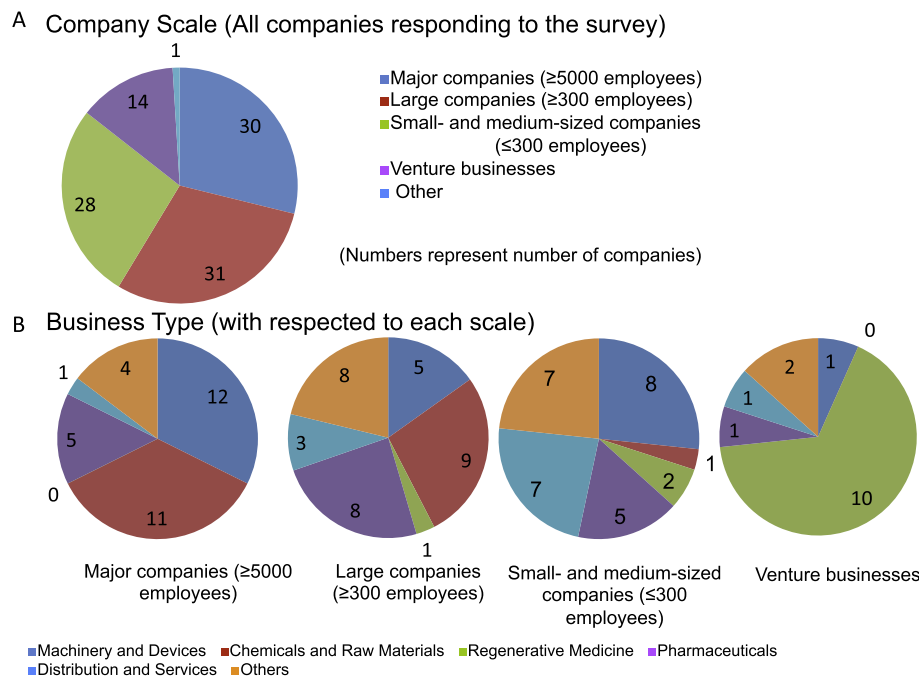


Fig. 1. Background of responders: Company scale and business. **A. Company scales of responders.** Indicated numbers show numbers of responder companies fitting into respective options. Company size is distributed almost uniformly. **B. Type of business in each scale.** Most of the major companies were in the machinery, devices, chemicals, raw materials and related industries, while the smaller-sized companies tended to be in the regenerative medicine industry.

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