



## Original Article

# Human resources required in the field of regenerative medicine: A follow-up of the Japanese survey in 2015

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## ABSTRACT

In 2015, we conducted a survey of the corporate members of FIRM on the human resources and training required in the field of regenerative cell therapies and reported the results in this journal. After that, industrialization of regenerative medicine has progressed and some cell products have been approved, and infrastructures, such as laws and educational systems, have been improved. To capture the changing demands for human resources in response to the shift in social circumstances, we conducted another survey. Consequently, now, there is an increasing demand for highly specialized skills and knowledge in the field of regenerative medicine. Furthermore, it was found that QA/QC managers and specialists of pharmaceutical affairs are strongly demanded, rather than technicians of cell culture. In addition, it became evident that there are still relatively few companies that have established their own internal education systems, and, in most cases, employees are trained by senior staff. The establishment of efficient education systems in public institutions and academic societies is desired.

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## 1. Introduction

In 2015, we conducted a survey of the corporate members of The Forum for Innovative Regenerative Medicine (FIRM) on the human resources and training required in the field of regenerative cell therapies and reported the results in this journal [1]. In those days, although some trials of regenerative medicine had been started, mainly in academic institutions, industrialization was called for in order to share the benefits of these therapies with a greater number of patients. For a sustainable supply of safe and high-quality products, standardization of manufacturing technology and quality control was needed, and the government and private sector rushed to build infrastructure and develop regulatory systems. In Japan, two laws were established in November 2014, The Act on the Safety of Regenerative Medicine and The Act on Pharmaceuticals and Medical Devices (PMD Act) [2–4]. On the other hand, for industries just starting or planning to start production of regenerative

medicine-related products, securing and fostering talented personnel were urgent issues to keep up with the newest and optimized technologies ensuring compliance. The Japanese Society of Regenerative Medicine was planning to establish educational systems, and discussions were held within the society regarding what sort of personnel should be nurtured, what kind of system should be constructed to achieve that, and what kind of training should be conducted within that system. In 2016, with a plan to construct a cross-sectional education system in academia, “The Training Consortium in Regenerative Medicine” was organized between Osaka University, Kyoto University, and Tokyo Medical and Dental University, commissioned by the Ministry of Education, Culture, Sports, Science and Technology-Japan, and FIRM joined as a cooperating body.

Against this backdrop, members of The Training Consortium in Regenerative Medicine and FIRM collaboratively conducted a questionnaire survey among participating companies in FIRM to determine what kinds of personnel and education are required. We received replies from 110 of the 175 companies, a very high recovery rate of 63% that reflected the high level of interest among FIRM member companies in training personnel in this field. Skilled experts not only in cell processing, but also in pharmaceutical affairs, patents, cell biology, and quality management, were required. Interestingly, the large majority of responders considered some kind of qualification or license to be unnecessary for talent

*Abbreviations:* QC, quality control; QA, quality assurance; iPS, induced pluripotent stem; CAR-T, chimeric antigen receptor-T; GMP, good manufacturing practice; PMDA, Pharmaceuticals and Medical Devices Agency; IND, investigational new drug; PCR, polymerase chain reaction; FDA, Food and Drug Administration.

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acquisition. However, they expected some public training system to be established.

Six years have passed, and several regenerative medicine-related products have been launched. There has also been an increase in the number of pharmaceutical companies involved in the development of iPS cells and other cell-based products. Furthermore, immune cell therapies with CAR-T cells have been commercialized all over the world [5,6], which has brought a revolution in the field of oncology. Regulatory systems have also been further organized and, within The Japanese Society for Regenerative Therapy (JSRM) and FIRM, efforts have been made to establish certification systems for cell manipulation technicians and physicians, publish textbooks, and develop e-learning systems, among other methods, to build an educational infrastructure [7].

How have the expectations for human resources and its cultivation changed in the midst of a constant flux of regenerative medicine? I conducted another survey on the needs for personnel in regenerative medicine to answer this question in partnership with Education Implementation Committee of FIRM.

## 2. Methods

This questionnaire study was conducted by the education board at FIRM to survey the special needs for human resources in the field of regenerative medicine. In 2015, from November 2–16, we conducted the previous survey of required human resources in regenerative medicine. We tried the same kind of investigation among FIRM members. This survey was conducted from January 26 to February 28, 2022. An e-mail invitation to respond to the questionnaire on the linked website in REDCap (<https://www.project-redcap.org>), an electronic data capture tool, was sent to all full members and supporting members of FIRM. 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 to some responses. Answers were collected and statistically analyzed on the REDCap system, and the processed data was downloaded in EXCEL software.

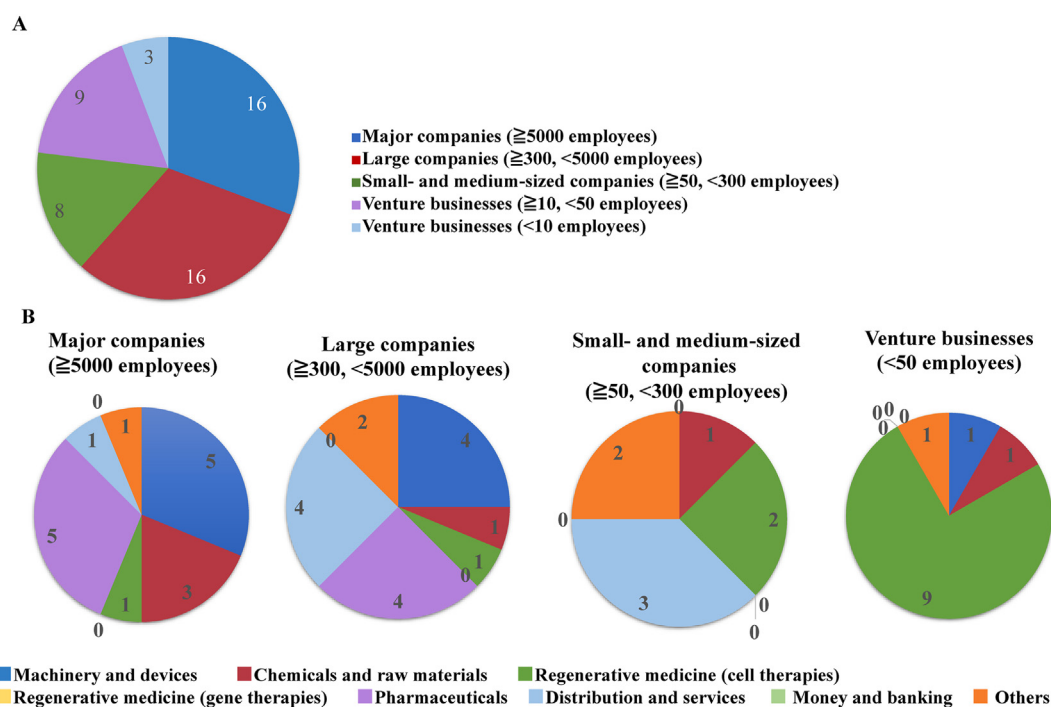
## 3. Results

### 3.1. Background

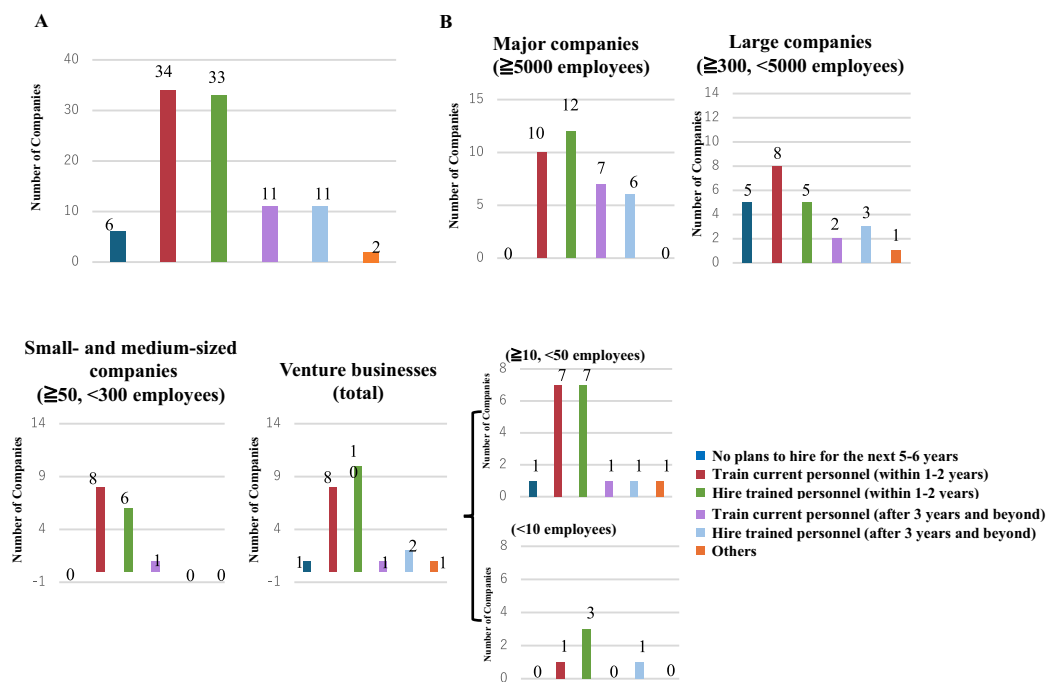
Responses were obtained from 52 of the 215 companies, a response rate of 24%, much smaller than the 63% for the survey conducted in 2015. Breaking the data down by scale of business, the number of major companies ( $\geq 5000$  employees) was 16 (30.8%), large ( $\geq 300, < 5000$ ) was 16 (30.8%), small ( $\geq 50, < 300$ ) was 8 (15.3%), venture 1 ( $\geq 10, < 50$ ) was 9 (17.3%), and venture 2 ( $< 10$ ) was 3 (5.8%), which was not so different from the breakdown in 2015. On the other hand, based on the business type, the ratio of regenerative medicine and pharmaceutical was 42.3% (22/52: regenerative medicine 13/52 = 25.0% and pharmaceuticals 9/52 = 17.3%), much larger than the 28.6% (32/112: regenerative medicine 13/112 = 11.6% and pharmaceuticals 19/112 = 17.0%) in 2015. This result does not reflect the breakdown of participating companies of FIRM. However, it appears to indicate an interest in talent development within each respective company. Although companies involved in peripheral industries, such as machinery and device or chemicals and raw materials, were 2/3 in 2015, major pharmaceuticals dealing directly regenerative medicine or being interested in this field and venture businesses of regenerative medicine responded to this survey (Fig. 1). Regenerative medicine is transitioning from infrastructure development towards implementation, and this trend is likely reflected in the interest within the education system.

### 3.2. Plans for personnel training and hiring

Participants were allowed to choose up to three of six options regarding future personnel training or hiring plans for regenerative fields (Fig. 2). 65% of companies were planning to train current



**Fig. 1. Backgrounds of responding companies.** A Company scale. The number of responding companies fitting into the respective options is shown. Company size is distributed almost uniformly. B Type of business in each scale. The types of businesses are categorized and color-coded as indicated. The number of categorized responders is noted.



**Fig. 2. Plans for personnel training and hiring.** Responding companies were asked if they were planning to train current employees or to hire already trained personnel. They were asked to choose up to three from the following options: 1) No plans to hire for the next 5–6 years; 2) Train current personnel within 1–2 years; 3) Hire trained personnel within 1–2 years; 4) Train current personnel after 3 years and beyond; 5) Hire trained personnel after 3 years and beyond; 6) Other. **A** Total responders. **B** Responders in each business scale.

employee within 1–2 years and 63% were to hire trained personnel, while in 2015, 79% of responders chose “train within 1–2 years” and 53% chose “hire within 1–2 years”. Many of the companies were planning training in-house rather than hiring expert personnel in 2015. In contrast, in 2022, even major companies demanded highly specialized human resources, which may reflect the lack of adequate training systems and trainers in this developing field. As observed in 2015, smaller companies showed a tendency of sooner requirement of specialized resources.

### 3.3. Plans for training programs and methods

Again, participants were allowed to choose up to three alternatives about the programs and measures of training their employees (Fig. 3). Interestingly, in addition to the skill practice in cell processing, classroom lectures in other fields of cell culture techniques, such as GMP, pharmaceutical affairs, intellectual property management, or quality management, were being planned. Among the skill practices of cell culture, both large and small companies were planning or practicing leader development training rather than training for beginners.

### 3.4. Human resources required

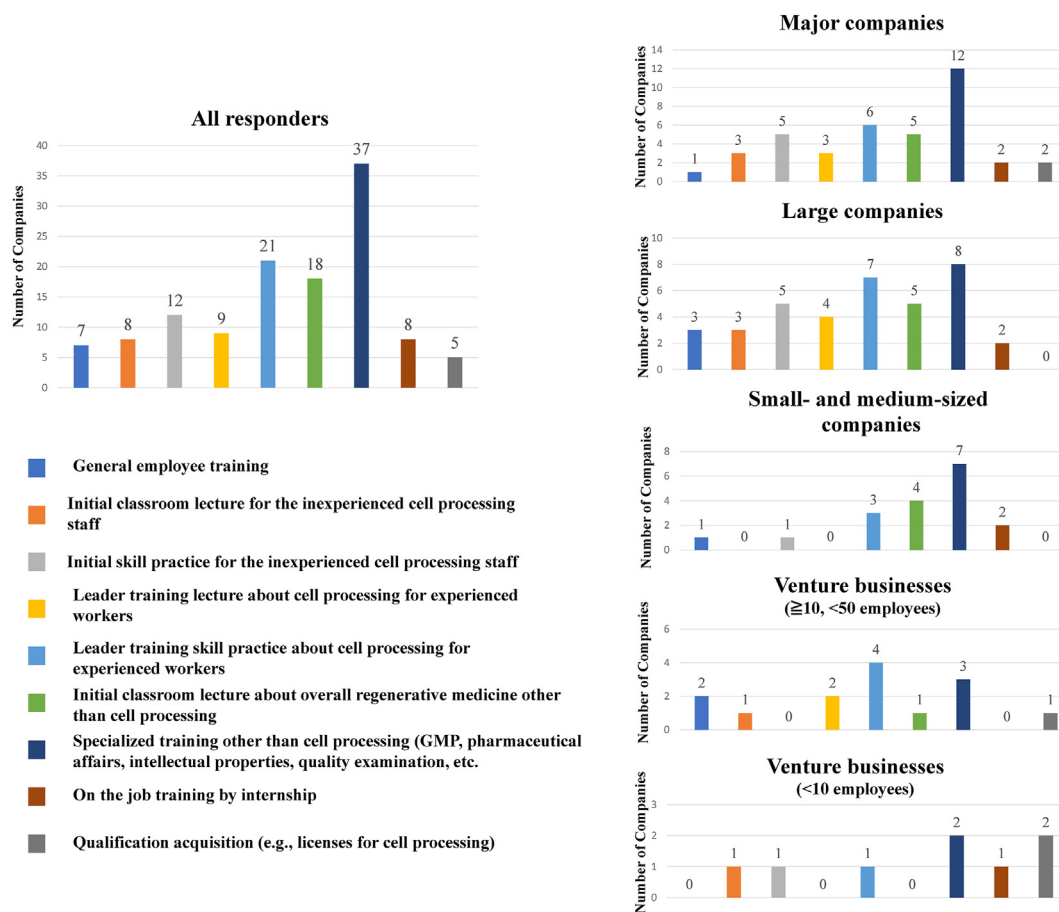
We conducted a survey on what type of personnel these companies were seeking, allowing multiple replies. Participants were asked about the needs for personnel and the needs for experience in various job types. First, needs in research, production, and management were surveyed. Personnel in QC/QA management sections were mostly needed, but half of the company selected “no need” for aseptic production managers (Fig. 4A). On the other hand, researchers for basic technology development and research assistants, rather than researchers with masters or doctoral degrees, were demanded regardless of experience. However, for QC/QA managers, experienced personnel were needed. Next, in the fields

of product development, sales, and business development, the needs for personnel in product design and planning, project management, pharmaceutical affairs, intellectual property, standardization of products, sales planning, and marketing were required. As shown in Fig. 4A, the personnel in product design and planning, project management, and particularly pharmaceutical affairs were in higher demand.

The next questions were on individual techniques, knowledge, and experiences required by personnel in each field. For biological and molecular biology experiments, more than half of the responders said they would prefer personnel to have knowledge and experience in flow cytometry, whereas gene manipulation and genomic analysis were selected by only four companies (Fig. 4B). For cell culture techniques, a very broad range of expertise was in demand, just as in 2015. It is interesting that the ability to perform basic assays and procedures, including cell culture of mesenchymal cells, was required rather than higher technologies, such as the foundation of ES cells or iPS cells and virus cultivation (Fig. 4B). Although we asked about experience in animal experimentation at various levels, the need for people with animal experimentation experience was limited, especially in middle/large animals and primates (Fig. 4B). In the fields of development and production of cell/gene products, expertise in negotiation with regulatory authorities, standardization of quality, and GMP production was highly demanded, but experiences in pharmaceutical or chemical products were surprisingly in less demand. Furthermore, within negotiation with regulatory authorities, experience in PMDA consultation meetings and applications for approval were highly demanded and, interestingly, there were some companies requiring expertise in applications for IND (Fig. 4B).

### 3.5. Need for certification

Finally, we asked what kind of system or certification would be required for human resource development in regenerative



**Fig. 3. Planned training program and education methods.** All responders were asked what kind of training they were planning to perform for their employees. Participants were allowed to choose up to three alternatives. Left, total answers from all responders. Right, the answer in each business scale. Options are shown at the bottom of the figure.

medicine. Four out of five participants replied that certifications were not required, approximately the same proportion as in 2015. In particular, 100% of major and small- and medium-sized companies felt them to be unneeded. Among the required licenses, pharmacists were most selected by large companies and licenses in wider fields were requested by venture companies (Fig. 5A).

### 3.6. Education systems in regenerative medicine

For the question, “what kind of education system do you have in your company?”, more than half of the responding companies answered that they do not have any education systems in-house and technique and knowledge were instructed by senior colleagues. Seven of the 52 companies had in-house educational systems in the regenerative field, mainly for cell culture. Some of the others (9/52) were embracing external educational institutions or systems (Fig. 5B).

### 3.7. Comprehensive research center for regenerative medicine

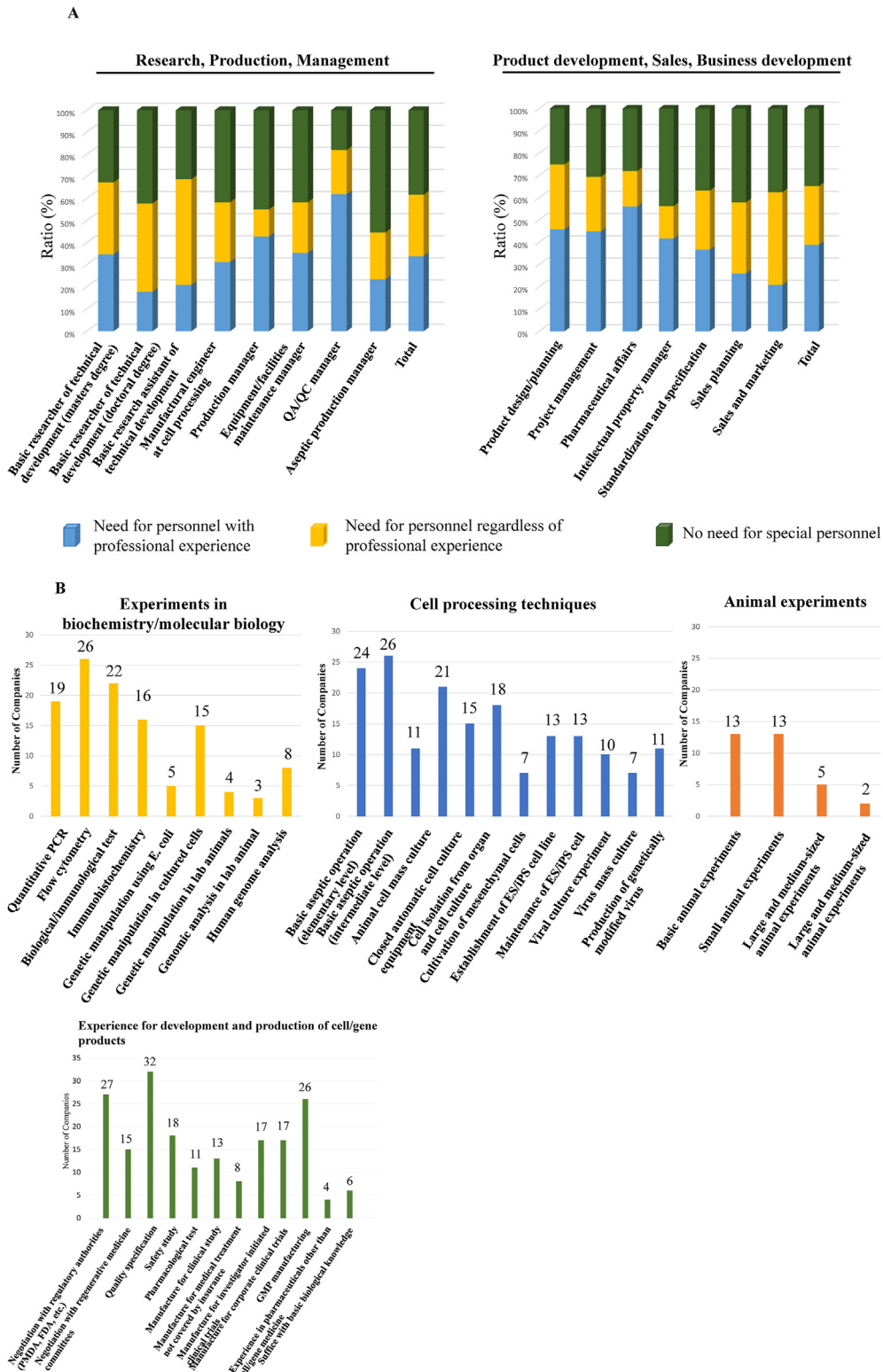
The last question was about the demands for a comprehensive research center for regenerative medicine. Thirty-four (65.3%) of the companies answered that they want to utilize such research centers, if any, compared to 75% in 2015. Some of the companies answered that they will utilize them if they have some courses available about specific issues for individuals lacking in such knowledge or techniques. Companies that answered “hoping to use” hoped to utilize mainly education and quality management systems, and some answered laboratories and cell banks (Fig. 5C).

## 4. Discussions

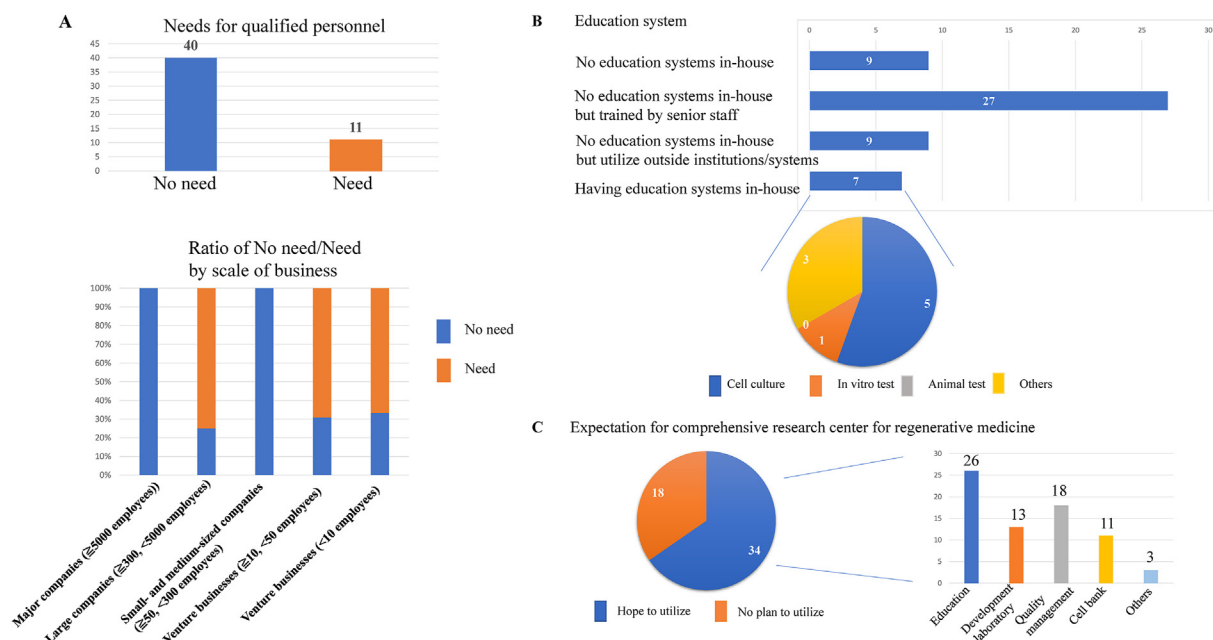
In the field of regenerative medicine, a substantial portion of manufacturing products are still dependent on manpower, and there is still strong demand for human resources with technical experience and knowledge in cell culture. In 2015, two laws have established in Japan which accelerated industrialization in regenerative medicine. The lack of human resources has been considered an important factor in the inhibition of industrialization. As the standardization of cell processing technologies was an urgent necessity, education systems for cell culture engineers have been established at some academic societies. However, as the phase of development evolves, the need for specialists with a broader range of knowledge and experience has increased. The industrialization of regenerative medicine was initially driven by the experience and knowledge from the pharmaceutical industry, but with the establishment of specialized laws focused on regenerative medicine and with the development of novel technologies in this field, there has been an increasing demand for professionals with specific knowledge and experience in regenerative medicine.

Different countries around the world have been developing regenerative medicine by harnessing their respective strengths, and leading companies worldwide are fiercely competing, particularly in the field of immune cell therapy. In Japan, the rapidly changing global landscape surrounding regenerative medicine calls for the development of globally-oriented professionals who can catch up with and surpass these changes.

Compared with the study in 2015, more companies were looking in 2022 to hire specialists with experience within 1–2



**Fig. 4. What kind of personnel needed in companies related to regenerative medicine.** **A** Needs for personnel with/without professional experience in each job function. Responders were asked whether they need personnel in each specific field with professional experience allowed to choose multiple options as they like. The percentage of responders who answered, “need for personnel with professional experience”, “need for personnel regardless of professional experience”, or “no need for personnel” in each job type in the field of research, production, and management is on the left, and in the field of product development, sales, and business development on the right. **B** Specific skills and experiences required for personnel. Responders were asked to choose “need” or “no need” for each item of technique or experience. Vertical bars show the numbers of responders who answered “need”.



**Fig. 5. Needs for qualification, education system, and public support for regenerative medicine.** **A** Need for qualification of employees. Top, the numbers of responders that answered “no need” are indicated in blue, and “need” in orange. Bottom, the ratios of “no need” and “need” are presented by business scale. **B** Application of education system in the responding companies. Responders were asked whether they have a training system in-house or utilize an outside system. The responders who answered “in-house” were further asked about the contents of system. **C** Expectations for the research center for regenerative medicine. For the last question, whether they hope to utilize on not the research center for regenerative medicine (left) and, if they hope, the equipment or systems they would like to use within the center (right) were explored with multiple choice.

years, which means that industries look for personnel who can hit the ground running. Although companies dealing in regenerative medical products have been increasing, there have not been sufficient educational systems in-house or outsourcing, and the majority of employees have been trained for each by senior colleagues.

There are some expectations, particularly in terms of personnel development, for the establishment of effective and authorized education systems in public institution or academic societies.

**Ethics approval and consent to participate**

This article does not contain any studies with human participants or animals.

**Consent for publication**

Not applicable, because there is only one author.

**Availability of data and material**

The data that support the findings of this study are available from the author upon reasonable request.

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**Author's contributions**

The author takes full responsibility for all aspects of this research paper.

**Declaration of competing interest**

This paper has not been published elsewhere in whole or in part. There are no ethical/legal conflict involved in the article.

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